

Virginia Title V Operating Permit

Until such time as this permit is reopened and revised, modified, revoked, terminated or expires, the permittee is authorized to operate in accordance with the terms and conditions contained herein. This permit is issued under the authority of Title 10.1, Chapter 13, §10.1-1322 of the Air Pollution Control Law of Virginia. This permit is issued consistent with the Administrative Process Act, and 9 VAC 5-80-50 through 9 VAC 5-80-300 of the State Air Pollution Control Board Regulations for the Control and Abatement of Air Pollution of the Commonwealth of Virginia.

Authorization to operate a Stationary Source of Air Pollution as described in this permit is hereby granted to:

Permittee Name:	Merck & Co., Inc. (Stonewall Plant)
Facility Name:	Merck & Co., Inc. (Stonewall Plant)
Facility Location:	4 miles South of Elkton on VA Route 340 Rockingham County, Virginia
Registration Number:	80524
Permit Number:	VRO80524

November 1, 2006

Effective Date

October 31, 2011

Expiration Date

R. Bradley Chewning

Regional Director, Valley Region

October 27, 2006

Signature Date

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Source Testing Report Format

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I. Facility Information

Permittee

Merck & Co., Inc. (Stonewall Plant)
2778 South East Side Highway
Elkton, Virginia 22827

Responsible Official

Mr. Charles F. Vencill, Ph.D.
Plant Manager

Facility

Merck & Co., Inc. (Stonewall Plant)
4 miles South of Elkton on VA Route 340
Rockingham County, Virginia

Contact Person

Ms. Barbara S. Wunder.
Director, Safety and Environment
(540) 298-4046

County-Plant Identification Number: 51-165-0001

Facility Description:

NAICS 325411 (formerly SIC 2833) – Medicinal Chemicals and Botanical Products
NAICS 325412 (formerly SIC 2834) – Pharmaceutical Preparation Manufacturing

Merck & Co., Inc. (Stonewall Plant) is involved in the manufacture of various pharmaceutical intermediates and products.

II. Emission Units

Equipment to be operated consists of:

Emission Unit ID	Emission Unit Description	Applicable Permit Date
B	Powerhouse: <ul style="list-style-type: none">- backup distillate oil-fired boiler (4)- natural gas-fired boilers (with distillate oil or propane backup) (7 & 8)	2/10/1998 administratively modified 8/8/2001 modified 9/18/2006
C	Internal Combustion Engines	2/10/1998 administratively modified 8/8/2001 modified 9/18/2006
D	Production Process Units	2/10/1998 administratively modified 8/8/2001 modified 9/18/2006
E	Sludge Dryer	2/10/1998 administratively modified 8/8/2001 modified 9/18/2006

HAP equipment to be operated consists of*:

Emission Unit ID	Stack ID	Emission Unit Description	Size/ Rated Capacity	Pollution Control Device (PCD) Description	PCD ID	Pollutant Controlled	Applicable Permit Date
Carbidopa Process	Unit Ref. 11	Pharmaceutical production process equipment		Scrubbers and Thermal Oxidation Units	SCR-301, -535, -615/616, 634/3500 & 2546 and TOU-2542 & RE-3501	Hazardous Air Pollutants (HAPs)	N/A
MK-476	Unit Ref. 22	Pharmaceutical production process equipment		Scrubbers and Thermal Oxidation Unit	SCR-2546 and TOU-2542	HAPs	N/A
Indinavir (Crixivan®)	Unit Ref. 21	Pharmaceutical production process equipment		Scrubbers and Thermal Oxidation Unit	SCR-2546, 1427/1427A& 301 and TOU-2542	HAPs	N/A
Central Solvent Recovery	Unit Ref. 41-42	Solvent recovery in support of pharmaceutical production processes		Scrubbers and Thermal Oxidation Unit	SCR-1000, TOU-2542/SCR-2546	HAPs	N/A
MK-991	Unit Ref. 81	Pharmaceutical production process equipment		Scrubber	SCR-9050	HAPs	N/A
Primaxin for Recovery	Unit Ref. 75	Pharmaceutical production process equipment		N/A	N/A	N/A	N/A
Imipenem	Unit Ref. 73	Pharmaceutical production process equipment		N/A	N/A	N/A	N/A
Cilastatin	Unit Ref. 72	Pharmaceutical production process equipment		N/A	N/A	N/A	N/A
Sodium Bicarbonate	Unit Ref. 74	Pharmaceutical production process equipment		N/A	N/A	N/A	N/A
Dorzolamide	Unit Ref. 23	Pharmaceutical production process equipment		Scrubbers and Thermal Oxidation Unit	TOU-2542/SCR-2546, SCR-1500	HAPs	N/A
TA-120, TA-121	Unit Ref. F	Wastewater storage tanks		Tank Covers	TA-120 Cover, TA-121 Cover	HAPs	N/A
Misc. Sources	-	Support services for pharmaceutical production process equipment (such as: stationary internal combustion engines, fugitives, lab hoods, boilers, gasoline tanks, and materials used in maintenance, repair, and construction activities, etc.)		N/A	N/A	N/A	N/A

*This table is provided for informational purposes only, and is not an applicable requirement.

III. Facility Wide Conditions (Project XL)

A. Limitations

1. Site-wide Emission Caps

- a. **Total Criteria Pollutant Emissions Cap:** The total criteria pollutant emissions cap (total emissions cap) is 1202 tons per year (TPY). The criteria pollutants included in the cap are the following: ozone (using volatile organic compounds (VOCs) as surrogate), sulfur dioxide (SO₂), particulate matter with aerodynamic diameter less than 10 microns (PM-10), carbon monoxide (CO), and oxides of nitrogen (NO_x).
- b. **SO₂ cap:** The SO₂ cap is 539 TPY.
- c. **PM-10 cap:** The PM-10 cap is 46 TPY.
- d. **NO_x cap:** The NO_x cap is 262 TPY.
- e. **Adjustments to the Site-wide Emissions Caps**

(1) Adjustments for criteria pollutant regulations

Prior to the compliance date of a criteria pollutant regulation, including New Source Performance Standards (40 CFR 60 and VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 5 (9 VAC 5-50-400 et seq.)), to which the site or a source at the site is newly subject, the permittee will either plan to implement the regulation as written by the compliance date, or adjust the site-wide emissions caps as follows:

- (a) The permittee shall determine the reduction in total actual emissions that would result from complying with the regulation on the compliance date. The total reduction will be based on the site's operations and production rate corresponding to the time period defined by the highest emission point (HEP) or another more appropriate emission rate, as agreed upon by the regulatory administering agency and the permittee.
- (b) Proposed adjustment of site-wide emission caps: site-wide emission caps will be proposed to be adjusted as follows:
 - (i) The SO₂ cap reduced by the reduction in total actual emissions of SO₂ that would result from complying with the new regulation.

- (ii) The PM-10 cap reduced by the reduction in total actual emissions of PM-10 that would result from complying with the new regulation.
- (iii) The NO_x cap reduced by the reduction in total actual emissions of NO_x that would result from complying with the new regulation.
- (iv) The total emissions cap reduced by the reduction in total actual emissions of CO or VOCs, as appropriate, that would result from complying with the new regulation.

(c) Approval of cap adjustment:

- (i) The permittee will submit the emission reduction determination and rationale to the regulatory administering agency for review and approval on a date prior to the compliance date of the regulation which is no later than 120 days for new regulations, or no later than 90 days for existing regulations to which the site or a source at the site is newly subject. The permittee shall provide additional documentation of the reduction estimate in a timely manner if requested. If the permittee fails to comply with the requirements of this paragraph, the permittee shall comply with the regulation as written.
- (ii) The emission reduction determination will be considered approved by the administering agency unless the permittee is notified in writing within 60 days of the initial notification provided in Condition III.A.1.e.(1).(c).(i).
- (iii) If the regulation is administered by EPA under a Federal Implementation Plan (CAA Section 110) or if it is an NSPS other than Subpart Kb (40 CFR 60.110b et seq.), the permittee shall implement the regulation as written by the compliance date if:
 - (a) EPA determines that compliance with the regulation instead of a cap adjustment is necessary for achieving the objectives of the regulation, and
 - (b) EPA notifies the permittee in writing within 60 days of the initial notification in Condition III.A.1.e.(1).(c).(i).

If the regulation is NSPS Subpart Kb, including associated provisions of Subpart A, this subparagraph would not apply.

- (iv) Except as provided in Condition III.A.1.e.(1)(c)(iii), if it does not agree with the permittee's estimate provided in III.A.1.e.(1)(c)(i), the administering agency shall provide an alternate reduction estimate based on the site's operations and production rate as described in III.A.1.e.(1)(a) and accepted emission estimation methods described in Table I.

Table I. Calculation Techniques Used to Determine Site-Wide Emissions.

Emission Sources	Methods of Calculation				
	VOC	SO ₂	PM-10	NO _x	CO
Process Vents	1,2	2	2	2	2
Internal Combustion Sources	2,6,7	2,6,7	2,6,7	2,6,7	2,6,7
External Combustion Sources	2,6,9	2,6,9	2,6,9	2,6,8,9	2,6,9
Natural Gas-Fired Boilers	2,6,10	2,6,10	2,6,10	2,6,8,10	2,6,10
VOC Bulk Storage Tanks	1,2,6	2	2	2	2
Solvent Recovery	2,4	2	2	2	2
Equipment Leaks	2,3	2	2	2	2
Wastewater Treatment	2,5	2	2	2	2

Key to Methods of Calculation:

1. 1978 Control Techniques Guideline (CTG), EPA; 1994 Alternative Control Techniques (ACT), EPA
2. Engineering Calculations
3. Site – Specific Emission Factors based on site-generated monitoring data approved for use by the VADEQ
4. B-JAC Condenser Model
5. Toxchem Model, approved for use by the EPA
6. EPA AP-42 5th Edition, most current update as per Condition III.B.2.c.(2)
7. Vendor Emission Data
8. Actual NO_x data from CEMs or PEMs
9. Available stack test data from comparable sources
10. Stack test performed on unit

- (v) Except as provided in Condition III.A.1.e.(1)(c)(iii), the parties will seek agreement on the reduction estimate that represents the reduction that would be effected by the regulation. Until an agreement is reached, the site shall operate with the site-wide emissions caps reduced by the amount determined by the permittee in Conditions III.A.1.e.(1)(a) and III.A.1.e.(1)(b), and shall be deemed to be in compliance with the regulation.
- (vi) Except as provided in Conditions III.A.1.e.(1)(c)(iii) and III.A.1.e.(1)(c)(v), if the parties have not obtained agreement on the appropriate reduction estimate within three months of

the administering agency's response in III.A.1.e.(1)(c)(ii), the permittee shall have the option of either:

- (a) Adjusting the site-wide emissions caps by amounts determined by the administering agency in III.A.1.e.(1)(c)(iv), or
- (b) Complying with the regulation as written no later than a date agreed upon by the parties which shall be no later than 12 months after the compliance date of the regulation.

(d) The site-wide emissions caps will be reduced as described in Condition III.A.1.e.(1)(b).

(e) The adjustments to the site-wide emissions caps will represent compliance with the regulation.

(2) Adjustments for Hazardous Air Pollutant (HAP) Regulations

No adjustment of the emissions caps shall be required when complying with applicable HAP regulations.

f. Operating Under the Emission Caps

(1) Compliance with Emission Caps

(a) The site's actual emissions of criteria pollutants shall not exceed the total emissions cap established in Condition III.A.1.a..

(b) The site's actual emissions of SO₂, PM-10, and NO_x shall not exceed the individual pollutant caps established in Conditions III.A.1.b, III.A.1.c, and III.A.1.d.

(c) Compliance with the total emissions cap and individual pollutant caps shall be determined by comparing the specific cap to the 12-month rolling total for that cap. Compliance with the total emissions cap and individual pollutant caps shall be determined within two months of the end of each month based on the prior 12 months. The permittee shall use the calculation techniques identified in Table I to calculate site-wide actual criteria pollutant emissions.

(2) Installation of controls for significant modifications and significant new installations

- (a) Condition III.A.1.f.(2) applies to significant modifications and significant new installations. Significant modifications for the purposes of this section are defined as changes to an existing process unit that result in an increase of the potential emissions of the process unit after consideration of existing controls of more than the significance levels listed in Condition III.A.1.f.(2)(b). Significant new installations for the purposes of this section are defined as new process units with potential emissions before controls that exceed the significance levels listed in Condition III.A.1.f.(2)(b). For purposes of this section, potential emissions means process unit point source emissions that would be generated by the process unit operating at its maximum capacity.
- (b) Significance levels for determining significant modifications and significant new installations:

<u>Pollutant</u>	<u>Significance Level (TPY)</u>
VOC	40
CO	100
NO _x	40
SO ₂	40
PM-10	15

- (c) For any significant modification or significant new installation, the permittee shall install at the process unit, emission controls, pollution prevention or other technology that represents good environmental engineering practice in the pharmaceutical or batch processing industry, based on the emission characteristics (flow, variability, pollutant properties, etc.) of the process unit. Examples of emission controls that meet this requirement include, but are not limited to:
- Condensation for high concentration VOC streams
 - Thermal oxidation for low concentration high flow VOC streams
 - Carbon adsorption for low concentration low flow VOC streams
 - Water or caustic scrubbing for acid gases and water soluble compounds
 - Water or acid scrubbing for caustic gases
 - Dust collection (bag filters) or other particle removal for particulates

- Low NO_x technology for significant NO_x combustion sources

(3) Operation of listed control equipment

The permittee shall continue to operate the emissions control equipment listed in Table II as follows: the equipment shall be operated in a manner which minimizes emissions, considering the technical and physical operational aspects of the equipment and associated processes. This operation shall include an operation and maintenance program based on manufacturers' specifications and good engineering practice.

Table II. Operation of Listed Control Equipment.

Emission Unit	Control Device	Pollutant
General requirement for all air pollution control (APC) equipment: Maintain APC equipment in proper working order.		
Diesel generator	NO _x control	NO _x
Sludge dryer	Dust collector (DC-609)	PM-10
	Venturi scrubber (VS-390)	PM-10
Solvent recovery	Venturi/packed bed scrubber in solvent recovery (SCR-1000)	VOCs
CRIXIVAN [®]	Fabric filter boxes (Finishing) (VF-121, VF-185)	PM-10
Factory 2 (CRIXIVAN [®] , Montelukast, and Dorzolamide)	Thermal oxidizer (TOU-2542)	VOCs
	Scrubber (SCR-2546)	VOCs and acid gases
	Secondary brine condensers in solvent recovery (CN-102, CN-505/506, CN-702)	VOCs
	Conservation vents (bulk storage tanks)	VOCs
Lovastatin	Bulk storage tank conservation vent	VOCs
	Secondary brine condensers in solvent recovery (CN-203) and Building 43 (CN-911)	VOCs

(4) Prohibition on emissions trading

Emission reductions of criteria pollutants listed in Condition III.A.1.a shall not be credited for trade or sale to any other site. Nor shall the permittee increase its allowable emissions through acquisition of emissions credits from the open market or from any other site.

(5) Prohibition for acid rain opt-in program

The permittee shall not participate in the acid rain program under the "opt-in" provisions of Clean Air Act Section 410.

(6) Control requirements for certain units

- (a) Units that would otherwise be subject to requirements in 40 CFR 264 Subpart AA (40 CFR 264.1030 et seq.), or 40 CFR 265 Subpart AA (40 CFR 265.1030 et seq.), shall be controlled with a secondary brine condenser or thermal oxidizer, and monitored as specified in Condition III.B.2.
- (b) The permittee shall continue its maintenance and repair program (that resulted in the site-specific emission factors referenced in Table I) for all equipment components (valves, flanges, pumps, compressors, sampling connections) that are in contact with VOCs and/or volatile organics (volatile organics as defined in 40 CFR 264 and 265).
- (c) The permittee shall install and maintain covers with no visible holes, gaps, or other open spaces on all containers that would otherwise be regulated under 40 CFR 264 Subpart CC (40 CFR 264.1080 et seq.), or 40 CFR 265 Subpart CC (40 CFR 265.1080 et seq.).
- (d) The permittee shall install covers with no visible holes, gaps, or other open spaces on all storage/accumulation tanks that would otherwise be subject to the tank provisions of 40 CFR 264 Subpart CC (40 CFR 264.1080 et seq.), or 40 CFR 265 Subpart CC (40 CFR 265.1080 et seq.). Fixed roof tanks may be equipped with one or more conservation vents.
- (e) The permittee shall install covers with no visible holes, gaps, or other open spaces on hazardous waste treatment tanks that would otherwise be subject to the treatment tank provisions of 40 CFR 264 Subpart CC (40 CFR 264.1080 et seq.), or 40 CFR 265 Subpart CC (40 CFR 265.1080 et seq.). Such tanks shall either be equipped with a floating roof, or be vented to a brine condenser or thermal oxidizer and monitored as specified in Condition III.B.2.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 1 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

2. The natural gas-fired boilers (7 & 8) shall be equipped with low nitrogen oxide (NO_x) technology.
(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, 40 CFR 60.49b(u)(1)(i) and Section 2 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)
3. The approved fuels for boilers 7 & 8 are natural gas as the primary fuel and distillate oil or propane as backup fuels. Distillate oil is defined as fuel oil that meets the specifications for fuel oil numbers 1 or 2 under the American Society for Testing and Materials, ASTM D396-78 "Standard Specification for Fuel Oils."
(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454 and Section 2 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)
4. The approved fuel for boiler 4 is distillate oil. Distillate oil is defined as fuel oil that meets the specifications for fuel oil numbers 1 or 2 under the American Society for Testing and Materials, ASTM D396-78 "Standard Specification for Fuel Oils."
(9 VAC 5-80-110)

B. Monitoring and Recordkeeping

1. The permittee shall install, calibrate, maintain, and operate a continuous monitoring and recording system on the natural gas-fired boilers for measuring NO_x emissions discharged to the atmosphere using a continuous emissions monitoring system or a predictive emissions monitoring system. Monitoring shall be in accordance with Table III, Section B.2.
(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, 40 CFR 60.49b(u)(1)(ii) and Section 4 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)
2. The permittee shall comply with the monitoring, recordkeeping and reporting requirements specified in Table III. Monitoring, recordkeeping and reporting as prescribed in this section shall constitute the basis for the permittee's certification of compliance with the provisions of the PSD permit pursuant to Title V.
(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, 40 CFR 60.49b(u)(1)(ii) and Section 4 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

Table III. Monitoring, Recordkeeping, and Reporting Requirements.

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section A: Site-Wide Criteria Pollutant Emissions							
Cap calculations	A.1	N/A	Monthly	Monthly	Monthly	Record	12-month rolling total site wide criteria pollutant emissions
	A.2	N/A	Monthly	Monthly	Monthly	Record	12-month rolling total site wide SO ₂ , NO _x , PM-10, CO, and VOC emissions respectively
	A.3	N/A	Monthly	Monthly	Monthly	Record	Total emissions cap, SO ₂ cap, NO _x cap, PM-10 cap
	A.4	N/A	Monthly	Monthly	Monthly	Record	Current HEP
	A.5	N/A	Monthly	Monthly	Monthly	Record	Current reporting tier as defined in Condition III.B.2.a.
	A.6	N/A	Semi-annually	Semi-annually	Monthly	Report	12-month rolling total site wide criteria pollutant emissions for each month covered by report.
	A.7	SO ₂ , NO _x	Semi-annually	Semi-annually	Monthly	Report	12-month rolling total SO ₂ , NO _x , PM-10, CO, and VOC emissions, respectively for each month covered by report.
	A.8	SO ₂ , NO _x	Annually	Semi-annually	Monthly	Report	Total criteria pollutant emissions and SO ₂ , NO _x , and PM-10 emissions reduced from XL project since last report (difference between cap/subcap and actuals)

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
	A.9	SO ₂ , NO _x	Annually	Semi-annually	Monthly	Report	Total criteria pollutant emissions and SO ₂ , NO _x , and PM-10 emissions reduced from XL project since start of PSD permit (cumulative difference between cap/subcap and actuals)
	A.10	SO ₂ , NO _x	Annually	Semi-annually	Monthly	Report	Reporting tier as defined in Condition III.B.2.a for each month covered by report.
	A.11	SO ₂ , NO _x	Within one month of changing from a lower tier to a higher tier			Report	Reporting tier as defined in Condition III.B.2.a.
Cap adjustments	A.12	N/A	Monthly	Monthly	Monthly	Record	Any adjustments to total emissions cap or individual caps
	A.13	SO ₂ , NO _x	Annually	Semi-annually	Monthly	Report	Any adjustments to total emissions cap or individual caps, and explanation for adjustment
	A.14	N/A	Upon compliance date of new regulation			Record	Record decision whether to implement regulation as written or adjust cap under Condition III.A.1.e.(1)
	A.15	N/A	120 or 190 days prior to compliance date of new regulation selected for cap adjustment as required by Condition III.A.1.e.(1)(c).			Report	Report total criteria pollutant reduction resulting from regulation, HEP or alternate emission rate, and basis for estimate
Condition III.A.1.f.(2) Installations	A.16	N/A	Upon operation of any modification or new installation			Record	Calculations determining whether the process modification or new installation triggers Condition III.B.1.f.(2)(b) significance levels

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
	A.17	N/A	Within 45 days of operation of any significant modification or significant new installation			Report	Submit report describing the significant modification or significant new installation (as defined in Condition III.A.1.f.(2)), and the controls, pollution prevention or other technology employed to meet the requirements of Condition III.A.1.f.(2). If the method employed is not one of the methods listed in Condition III.A.1.f.(2)(c), include an explanation for the technology selected.
	A.18	N/A	Within 45 days of operation of any significant modification or significant new installation			Report	Submit report providing the following information: a schematic diagram showing the type and sequence of new equipment installed or modified, equipment identification numbers, location of the new installation or modification on the plant site, air pollution control equipment associated with the new installation or modification, and the total emissions of each criteria pollutant emitted from each piece of new or modified equipment.
Operation of Listed Controls (Condition III.A.1.f.(3))	A.19	N/A	Ongoing	Ongoing	Ongoing	Record	Record time control equipment listed in Table II is not operating while the controlled emissions unit is operating.

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
	A.20	N/A	Annually	Annually	Annually	Report	Percent time that each control device listed in Table II operated over the previous year.
Modeling Parameters	A.21	N/A	Upon request within reasonable time period			Report	Stack parameters and modeling inputs for sources of PM-10, NO _x and SO ₂ .
Section B: Powerhouse							
Natural Gas-Fired Boilers	B.1	N/A	Continuously	Continuously	Continuously	Monitor and Record	NO _x and opacity using CEMs or PEMs
	B.2	N/A	Monthly	Monthly	Monthly	Monitor and Record	Type and amount of fuel used
	B.3	N/A	Monthly	Monthly	Monthly	Record	Emissions based on stack test, NO _x CEM/PEM, emission factors and fuel usage
	B.4	SO ₂ , NO _x	Annually	Semi-annually	Monthly	Report	Emissions based on stack test, NO _x CEM/PEM, emission factors and fuel usage
	B.5	N/A	Monthly	Monthly	Monthly	Record	Percent time burning natural gas and backup fuel
	B.6	SO ₂ , NO _x	Annually	Semi-annually	Monthly	Report	Percent time burning natural gas and backup fuel
Backup oil Unit	B.7	N/A	Monthly	Monthly	Monthly	Monitor and Record	Amount and type of fuel used
	B.8	N/A	Monthly	Monthly	Monthly	Record	Emissions based on emission factors and fuel usage
Section C: Emergency Generators							
All units	C.1	N/A	Monthly			Record	Emissions based on emission factors, operation schedule and any non-scheduled event requiring operation of a unit for five days or more.

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
	C.2	N/A	Annually			Report	Emissions based on emission factors, operation schedule and any non-scheduled event requiring operation of a unit for five days or more.
	C.3	SO ₂ , NO _x		Monthly	Monthly	Monitor and Record	Time of operation
	C.4	SO ₂ , NO _x		Monthly	Monthly	Monitor and Record	Amount and type of fuel used
	C.5	SO ₂ , NO _x		Monthly	Monthly	Record	Emissions based on emission factor and fuel usage
	C.6	SO ₂ , NO _x		Semi-annually	Monthly	Report	Emissions based on emission factor and fuel usage
Powerhouse Generator	C.7	N/A	Annually	Annually	Annually	Monitor	Verify that original timing as set by the manufacturer has not been changed
Section D: Production Process Units							
	D.1	N/A	Monthly	Monthly	Monthly	Record	Changes to the process that affect the emission factor
	D.2	N/A	Monthly	Monthly	Monthly	Record	Maintain current process emission factors
	D.3	N/A	Monthly	Monthly	Monthly	Monitor and Record	WWTP influent flow, temperature and VOC constituent concentrations
	D.4	N/A	Monthly	Monthly	Monthly	Monitor and Record	Number of production units
	D.5	N/A	Monthly	Monthly	Monthly	Record	Emissions based on emission factor and number of production units
	D.6	SO ₂ , NO _x	Annually	Semi-annually	Monthly	Report	Emissions based on emission factor and number of production units

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
	D.7	SO ₂ , NO _x		Annually	Semi-annually	Report	Summary of changes to emission factors based on process modifications
	D.8	N/A	Annually	Annually	Annually	Report	Basis for point source emission factors (see example 1 below)
	D.9	N/A	Within 180 days of start-up of new unit operation			Record	Emission factor verification study for unit operations not included in the following list: Fill, Evacuation, Gas Sweep, Heat, Gas Evolution, Vacuum Distillation, Vacuum Drying, Tank Breathing

Example 1: Basis for Process Vent Emission Factor

For Each Process:

Step Number	Vessel I.D.	VOC Emissions (lb/step)
1	RE-101	0.1
2	RE-101	2.5
3	RE-101	20.0
4	TA-105	0.2
...
80	TA-308	0.3
Total	-	95.2 lb/production unit

Section E: Criteria Pollutant Control Equipment

Sludge Dryer dust collector (DC-609)	E.1	N/A	Continuously	Continuously	Continuously	Monitor	Differential pressure drop
	E.2	N/A	Once per day	Once per day	Once per day	Record	Differential pressure drop

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Sludge Dryer Venturi scrubber (VS-390)	E.3	N/A	Continuously	Continuously	Continuously	Monitor	Pressure drop and liquid flow
	E.4	N/A	Once per day	Once per day	Once per day	Record	Pressure drop and liquid flow
CRIXIVAN® fabric filters (finishing) (VF-121, VF-185)	E.5	N/A	Continuously			Monitor	Differential pressure drop across filter
	E.6	N/A	Once per batch			Record	Differential pressure drop across filter
Factory 2 thermal oxidizer (TOU-2542)	E.7	N/A	Continuously			Monitor and Record	Combustion chamber temperature
Factory 2 scrubber (SCR-2546)	E.8	N/A	Continuously			Monitor	Liquid flow and differential pressure drop
	E.9	N/A	Once per batch			Record	Liquid flow and differential pressure drop
Factory 2 secondary brine condensers in solvent recovery (CN-102, CN-505, CN-506, CN-702)	E.10	N/A	Continuously	Continuously	Continuously	Monitor	Exit vapor temperature or coolant flow and coolant exit temperature
	E.11	N/A	Once per batch	Once per batch	Once per batch	Record	Exit vapor temperature or coolant flow and coolant exit temperature
Lovastatin secondary brine condenser in solvent recovery (CN-203) and Building 43 (CN-911)	E.12	N/A	Continuously	Continuously	Continuously	Monitor	Exit vapor temperature or coolant flow and coolant exit temperature
	E.13	N/A	Once per batch	Once per batch	Once per batch	Record	Exit vapor temperature or coolant flow and coolant exit temperature

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Solvent recovery Venturi/packed bed scrubber (SCR-1000)	E.14	N/A	Continuously			Monitor	Liquid flow and differential pressure drop
	E.15	N/A	Once per batch			Record	Liquid flow and differential pressure drop
Carbidopa thermal oxidizer (RE-3501)	E.16	N/A	Continuously			Monitor	Combustion chamber temperature
	E.17	N/A	Once per batch			Record	Combustion chamber temperature
Carbidopa packed bed scrubber (SCR-634, SCR-3500)	E.18	N/A	Continuously			Monitor	Liquid flow and pH
	E.19	N/A	Once per batch			Record	Liquid flow and pH
Units that would otherwise be regulated under 40 CFR 264 Subpart AA or 265 Subpart AA controlled by a condenser	E.20	N/A	Continuously	Continuously	Continuously	Monitor	Coolant flow and coolant outlet temperature
	E.21	N/A	Once per batch	Once per batch	Once per batch	Record	Coolant flow and coolant outlet temperature
Units that would otherwise be regulated under 40 CFR 264 Subpart AA or 265 Subpart AA controlled by a thermal oxidizer	E.22	N/A	Continuously			Monitor and Record	Combustion chamber temperature

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
VOC and volatile organic ⁴ bulk storage tanks ≥ 10,000-gal capacity: conservation vent	E.23	N/A	Annually	Annually	Annually	Monitor	Verify conservation vent pressure setting at or above 0.030 psi
New condensers added under III.A.1.f.(2) of the permit	E.24	N/A	Continuously	Continuously	Continuously	Monitor	Coolant flow and coolant outlet temperature
	E.25	N/A	Once per batch	Once per batch	Once per batch	Record	Coolant flow and coolant outlet temperature
New non-catalytic thermal oxidizers added under III.A.1.f.(2) of the permit	E.26	N/A	Continuously			Monitor and Record	Combustion chamber temperature
New catalytic thermal oxidizers added under III.A.1.f.(2) of the permit	E.27	N/A	Continuously			Monitor and Record	Inlet temperature and temperature increase across catalyst bed.
New scrubbers added under III.A.1.f.(2) of the permit	E.28	N/A	Continuously			Monitor	Scrubber water flow and differential pressure
	E.29	N/A	Once per batch			Record	Scrubber water flow and differential pressure

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
New carbon adsorption systems added under III.A.1.f.(2) of the permit	E.30	N/A	Within 60 days of unit's initial startup			Record	Establish appropriate regeneration cycle based on breakthrough rate, and performance indicator (e.g., online time, number of batches, or breakthrough indicator)
	E.31	N/A	Once per batch			Record	Carbon performance indicator
New regenerative carbon adsorption systems added under III.A.1.f.(2) of the permit	E.32	N/A	Once per regeneration cycle			Monitor and Record	Regeneration medium mass flow during regeneration and carbon bed temperature after regeneration
New dust collection systems added under III.A.1.f.(2) of the permit	E.33	N/A	Continuously			Monitor	Differential pressure across filter
	E.34	N/A	Once per batch			Record	Differential pressure across filter
Each condenser at site with uncontrolled emissions > 8000 lbs/yr VOCs	E.35	N/A		Continuously	Continuously	Monitor	Coolant flow and coolant outlet temperature
	E.36	N/A		Once per batch	Once per batch	Record	Coolant flow and coolant outlet temperature
All non-catalytic thermal oxidizers at site	E.37	N/A		Continuously	Continuously	Monitor and Record	Combustion chamber temperature
All catalytic thermal oxidizers at site	E.38	N/A		Continuously	Continuously	Monitor and Record	Inlet temperature and temperature increase across catalyst bed.

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
All scrubbers at site	E.39	N/A		Continuously	Continuously	Monitor	Scrubber water flow and differential pressure
	E.40	N/A		Once per batch	Once per batch	Record	Scrubber water flow and differential pressure
All carbon adsorption systems at site	E.41	N/A		Within 60 days of unit's initial startup		Record	Establish appropriate regeneration cycle based on breakthrough rate, and performance indicator (e.g., online time, number of batches, or breakthrough indicator)
	E.42	N/A		Once per batch	Once per batch	Record	Carbon performance indicator
All regenerative carbon adsorption systems at site	E.43	N/A		Once per regeneration cycle	Once per regeneration cycle	Monitor and Record	Regeneration medium mass flow during regeneration and carbon bed temperature after regeneration
All dust collection systems at site	E.44	N/A		Continuously	Continuously	Monitor	Differential pressure across filter
	E.45	N/A		Once per batch	Once per batch	Record	Differential pressure across filter
Each condenser at site with uncontrolled emissions > 4000 lbs/yr VOCs	E.46	N/A			Continuously	Monitor	Coolant flow and coolant outlet temperature
	E.47	N/A			Once per batch	Record	Coolant flow and coolant outlet temperature
All condensers at site with uncontrolled emissions > 4000 lbs/yr VOCs	E.48	N/A			One-time ⁵	Monitor and Record	Confirm condenser performance with stack test or, where stack test has proven infeasible to determine performance efficiency, other engineering assessments may be used upon DEQ approval

Emission Unit		Pollutants subject to individual caps	Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
All thermal oxidizers at site	E.49	N/A			One-time ⁵	Monitor and Record	Perform stack test on unit to determine criteria pollutant emissions
All scrubbers at site	E.50	N/A			One-time ⁵	Monitor and Record	Confirm scrubber performance with stack test or, where stack test has proven infeasible to determine performance efficiency, other engineering assessments may be used upon DEQ approval
All carbon adsorption systems at site	E.51	N/A			One-time ⁵	Monitor and Record	Confirm carbon system performance with stack test or, where stack test has proven infeasible to determine performance efficiency, other engineering assessments may be used upon DEQ approval
All dust collection systems at site	E.52	N/A			One-time ⁵	Monitor and Record	Confirm dust collection system performance with stack test or, where stack test has proven infeasible to determine performance efficiency, other engineering assessments may be used upon DEQ approval

⁵ Within 6 months of reaching Tier III for the first time for existing equipment, and within 3 months of commencement of operation for new equipment, a stack test performed no more than 5 years prior to reaching Tier III may be used in place of a new test provided that the emission controls and operating conditions are still representative of those under which the prior test was conducted.

(III.B.2)

a. Reporting Tiers

(1) Tier I requirements are in effect under the following circumstances:

- (a) Actual criteria pollutant emissions for the last 12 months are determined to be greater than 0% and less than 75% of the total emission cap and during the startup period of the permit (the period between November 9, 2000 and July 12, 2001), and
- (b) Actual emissions of SO₂ or NO_x for the last 12 months are determined to be greater than 0% and less than 75% of the individual emissions cap for each pollutant.

(2) Tier II requirements are in effect under the following circumstances:

- (a) Except as provided in Condition III.B.2.a.(1)(a), actual criteria pollutant emissions for the last 12 months are determined to be equal to or greater than 75% and less than 90% of the total emission cap, or
- (b) Actual emissions of SO₂ or NO_x for the last 12 months are determined to be equal to or greater than 75% and less than 90% of the individual emissions cap for each pollutant. If actual emissions of SO₂ or NO_x for the last 12 months trigger Tier II requirements and total criteria pollutant emissions remain below Tier II (as determined according to Condition III.B.2.a.(2)(a)), only those Tier II-level provisions applicable to the triggering pollutant(s), as indicated in Table III, shall apply.

(3) Tier III requirements are in effect under the following circumstances:

- (a) Except as provided in Condition III.B.2.a.(1)(a), actual criteria pollutant emissions for the last 12 months are determined to be equal to or greater than 90% of the total emission cap, or
- (b) Actual emissions of SO₂ or NO_x for the last 12 months are determined to be equal to or greater than 90% of the individual emissions cap for each pollutant. If actual emissions of SO₂ or NO_x for the last 12 months trigger Tier III requirements and total criteria pollutant emissions remain below Tier III (as determined according to Condition III.B.2.a.(3)(a)), only those Tier III-level provisions applicable to the triggering pollutant(s), as indicated in Table III, shall apply.

b. Except as provided in Condition III.B.2.a.(1)(a), Tier I, II and III monitoring, recordkeeping and reporting requirements for SO₂, PM-10, NO_x, CO and VOCs are found in Table III.

c. Emission Calculation Techniques

(1) Table I specifies the emission calculation techniques to be used for each emission type at the site.

(2) If the AP-42 emission factors described in Table I are updated, and the project signatories fail to agree upon appropriate changes needed to incorporate these updated factors into the permit as provided in Condition VII.A.1.a, VADEQ may at its discretion initiate the following actions:

(a) Describe to the project stakeholders in writing that use of the updated AP-42 emission factor is important for the technical validity of the site's emission calculations.

(b) Obtain from the permittee:

(i) Confirmation that the emission source(s) at the site are the same type of sources as those for which the AP-42 emission factor applies, and

(ii) Agreement on how the emissions caps, HEP and current actual emissions should be adjusted to reflect the updated emission factor.

(c) Provided that agreement is reached in Condition III.B.2.c.(2)(b), initiate the permit modification procedure to incorporate the change into the permit.

d. Monthly Requirements

(1) Beginning on the first day of each month, the permittee shall perform the monitoring, recordkeeping and reporting requirements in Table III according to the applicable reporting tier specified in Condition III.B.2.a determined by the 12 month rolling total of criteria pollutant emissions, SO₂ emissions, or NO_x emissions of the period ending three calendar months prior to that date. The monthly calculations specified in Table III shall cover the period which ended two calendar months prior to that date.

(2) Example

- (a) By 3/1/97 calculate the 12 month rolling total of criteria pollutant emissions for 1/1/96 through 12/31/96.
 - (b) Assume 1/1/96 – 12/31/96 emissions total equals 80% of total emissions cap.
 - (c) Assume Tier I requirements were in effect 2/97 and prior.
 - (d) For the month of April 1997, Tier II monitoring, recordkeeping and reporting requirements would be in effect.
 - (e) Twelve month rolling total including the first month of Tier II data (from 4/97) will be calculated by 7/1/97 for period 5/1/96 through 4/30/97.
- e. Records required in this section shall be retained on site for at least five years.
- f. Adherence to Continuous Monitoring Requirements

This paragraph applies to each of the monitoring systems required by the PSD permit. Adherence to the requirement to monitor continuously shall be demonstrated by either Condition III.B.2.f.(1) or III.B.2.f.(2).

 - (1) Collection of at least 90% of the data required to be collected by the permit during any one month, or
 - (2) Collection of less than 90% of the data required to be collected by the permit during any one month, and either
 - (a) Verification and documentation through independent means sufficient to establish that the control device was operating properly during the period that the monitoring system failed to collect data, or
 - (b) The assumption for the purpose of emission calculations that the control device was not operating during the period that the monitoring system failed to collect data.
- g. HAP Monitoring and Emission Testing Requirements Under CAA Section 112(d)
 - (1) Compliance with monitoring requirements required for a particular control device under an applicable CAA 112(d) regulation, under the sections of Merck's Title V Operating Permit entitled "Facility-Wide Conditions for Hazardous Air Pollutants - Synthetic Minor Operation" and "Facility-Wide Conditions for Hazardous Air Pollutants – Major Source Operation",

where such requirements are more stringent than the applicable Table III monitoring requirement, shall constitute compliance with any Condition III.B.2 monitoring requirement applicable to that device.

(2) Compliance with emission testing requirements required for a particular control device under an applicable CAA 112(d) regulation shall constitute compliance with any Condition III.B.2 emission testing requirement applicable to that device.

h. In addition to the requirements in Condition X.D.4 for visible emissions and odor, the VADEQ shall be notified of each event involving malfunction or bypass or a control device listed in Table II or any new control device installed pursuant to Condition III.A.1.f.(2), if the total criteria pollutant emissions resulting from such event are expected to exceed 5% of the total emissions cap. This notification shall be provided no later than four daytime business hours after the determination of applicability of this section is made.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 4 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

C. Reporting

1. Reports shall be submitted as detailed in Table III.

(9 VAC 5-80-110)

2. Annual and Semi-Annual Reporting Requirements

a. On September 1 of each year, the permittee shall submit a semi-annual report for the six-month period ending June 30th if any tier reached during that period required a semi-annual report.

b. On March 1 of each year, the permittee shall submit a semi-annual report for the six-month period ending December 31st if any tier reached during that period required a semi-annual report.

c. On March 1 of each year, the permittee shall submit an annual report for the 12-month period ending December 31st.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 4 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

3. Reports required in Condition III.C.1 shall be submitted to the project signatories.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 4 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

4. Reports required in Condition III.C.2 shall contain certification by the site's responsible official that to his belief, based on reasonable inquiry, the information submitted in the report is true, accurate, and complete.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 4 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

5. Annual Progress Report

In addition to the reports otherwise required in this section, the permittee shall submit to the project stakeholders and to other parties an annual progress report. This report shall include a summary of the site's actual emissions and site-wide emission caps, emissions reduced as a result of the PSD permit, and other information about the site and the operation of the PSD permit.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 4 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

D. Testing

1. Within six months of reaching Tier III for the first time for existing equipment, and within three months of commencement of operation for new equipment when the site is operating subject to Tier III requirements, one-time stack tests or evaluations using an appropriate engineering calculation tool shall be performed on the following:

Emission Unit	Requirement
All condensers at site with uncontrolled emissions > 4000 lb/yr VOCs	Confirm condenser performance with engineering calculation tool or stack test
All thermal oxidizers at site	Perform stack test to determine criteria pollutant emissions
All scrubbers at site	Confirm scrubber performance with engineering calculation tool or stack test
All carbon adsorption systems at site	Confirm carbon system performance with engineering calculation tool or stack test
All dust collection systems at site	Confirm dust collection system performance with engineering calculation tool or stack test

A stack test performed no more than five years prior to reaching Tier III may be used in place of a new test provided that the emission controls and operating conditions are still representative of those under which the prior test was conducted.

(9 VAC 5-80-110 and Table 4.2 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

2. If testing is conducted in addition to the monitoring specified in this permit, the permittee shall use the following test methods in accordance with procedures approved by the DEQ as follows:

Pollutant	Test Method (40 CFR Part 60, Appendix A)
VOC	EPA Methods 18, 25, 25a
NO _x	EPA Method 7
SO ₂	EPA Method 6
CO	EPA Method 10
PM/PM-10	EPA Methods 5, 17
Visible Emission	EPA Method 9

(9 VAC 5-80-110)

IV. Facility Wide Conditions for Hazardous Air Pollutants – Synthetic Minor Operation

The limitations, monitoring, recordkeeping, reporting, and testing requirements below (Section IV) shall be replaced by the requirements of Section V (40 CFR 63 Subpart GGG) on January 1, 2008 and shall no longer apply after that date, unless the permittee provides notification delaying such transition according to Section V.

A. Limitations

1. Emissions Limits – Sitewide emissions of hazardous air pollutants (HAPs) shall be less than the limitations specified below:

Any individual HAP	9.9 tons/yr
Total HAPs	24.9 tons/yr

Sitewide HAP emissions shall be calculated monthly as the sum of each consecutive 12-month period.
 (9 VAC 5-80-110)

2. Emission Controls - HAP emissions from the manufacturing areas shall be controlled as indicated below:

Table IV. HAP control requirements

Process	Control Device
Carbidopa	Thermal Oxidizer Unit RE-3501 and TOU-2542 and Scrubbers SCR-634, SCR-3500, SCR-615, SCR-616, SCR-535, and SCR-2546
Unloading from aHCl railcar	SCR-301
Indinavir, MK-476, Dorzolamide	Thermal Oxidation Unit RE-2542 and Scrubbers SCR-1427 and SCR-1427A (Indinavir only), SCR-1500 (Dorzolamide only), and SCR-2546
Central Solvent Recovery	SCR-1000
MK-991	SCR-9050

Each control device shall be provided with adequate access for inspection and shall be in operation when the process is operating except during start-up,

shutdown, or malfunction, or when maintenance is performed on the control device and it is not practicable to shut down the process. The permittee shall keep records documenting periods of control device operation and periods of process operation during which the control device is not operating. The content and format of such records shall be arranged with the Director, Valley Region.
(9 VAC 5-80-110)

3. Emission Controls – Wastewater Treatment – Volatile HAP emissions from wastewater treatment shall be controlled by installation of fixed roof covers on two equalization tanks (TA-120 and TA-121). The covers shall be provided with adequate access for inspection.
(9 VAC 5-80-110)

B. Monitoring

1. Control Device Bypass Lines -If any of the closed-vent systems used to route HAP emissions from the processes listed in Table IV to the respective control devices contain bypass lines that could divert a vent stream containing HAPs away from the designated control device or an alternative control device, one of the following provisions shall be met:
 - a. The permittee shall install, calibrate, maintain, and operate a flow indicator that determines, at least once every 15 minutes, whether vent stream flow is present. A flow indicator means a device that indicates whether gas flow is, or whether the valve position would allow gas flow to be, present in a line. Records of the durations of periods of flow through such bypass routes shall be maintained and such periods shall be used to adjust HAP emission factors and calculations. The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream containing HAPs away from the designated control device or an alternative control device; or
 - b. The permittee shall secure the bypass line valve in the closed position with a car seal or lock-and-key type configuration. A visual inspection of the seal or closure mechanism shall be performed at least once every month to ensure that the valve is maintained in the closed position and the vent stream containing HAPs is not diverted through the bypass line.

Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this condition. In lieu of monitoring, the permittee may maintain documentation showing that a closed-vent system does not contain HAPs.

(9 VAC 5-80-110)

2. Leak Maintenance and Repair Program – The permittee shall continue its maintenance and repair program for all equipment components (pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems) that are in contact with HCl and/or organic HAPs.
(9 VAC 5-80-110)
3. Anhydrous HCl (aHCl) Leak Detection – Any pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems that operate in aHCl service for 300 hours or more during the calendar year shall be monitored in accordance with the frequencies below:
 - a. Once every two years if the percent leaking equipment/equipment components was less than 1.0% during the last required monitoring period. The permittee may comply with this requirement by monitoring at least 40% of the equipment/equipment components in the first year and the remainder in the second year. The percent leaking equipment/equipment components will be calculated for the total of all monitoring performed during the 2-year period.
 - b. If the permittee calculates less than 0.5% leaking equipment/equipment components from the 2-year monitoring period, the permittee may monitor the equipment/equipment components one time every four years. The permittee may comply with this requirement by monitoring at least 20% of the equipment/equipment components each year until all equipment/equipment components have been monitored within four years.
 - c. If during the last required monitoring period, the percent leaking equipment/equipment components was greater than 1.0%, monitoring shall be conducted annually until the percent leaking equipment/equipment components is less than 1.0%.
 - d. In lieu of conducting aHCl component monitoring, an annual pressure test may be conducted on equipment handling aHCl to determine the presence of leaks of aHCl. If the pressure test results indicate a leak is present, the leak rate shall be quantified using methods approved by the Director, Valley Region.
 - e. All aHCl monitoring equipment shall be operated in accordance with manufacturer's recommendations.

- f. Equipment in vacuum service is excluded from the requirements of this condition.

(9 VAC 5-80-110)

- 4. Leak Definition for aHCl – The instrument reading that defines a leak during aHCl leak detection is:

- a. Greater than or equal to 10,000 ppm for agitators, or
- b. Greater than or equal to 2,000 ppm for pumps, or
- c. Greater than or equal to 500 ppm for compressors, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems.

(9 VAC 5-80-110)

- 5. Organic HAP Leak Detection – Any pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems that operate in organic HAP service for 300 hours or more during the calendar year shall be monitored in accordance with the frequencies below:

- a. Once every two years if the percent leaking equipment/equipment components was less than 1.0% during the last required monitoring period. The permittee may comply with this requirement by monitoring at least 40% of the equipment/equipment components in the first year and the remainder in the second year. The percent leaking equipment/equipment components will be calculated for the total of all monitoring performed during the 2-year period.
- b. If the permittee calculates less than 0.5% leaking equipment/equipment components from the 2-year monitoring period, the permittee may monitor the equipment/equipment components one time every four years. The permittee may comply with this requirement by monitoring at least 20% of the equipment/equipment components each year until all equipment/equipment components have been monitored within four years.
- c. If during the last required monitoring period, the percent leaking equipment/equipment components was greater than 1.0%, monitoring shall be conducted annually until the percent leaking equipment/equipment components is less than 1.0%.

- d. In lieu of conducting organic HAP component monitoring, an annual pressure test may be conducted on equipment handling organic HAPs to determine the presence of leaks of organic HAPs. If the pressure test results indicate a leak is present, the leak rate shall be quantified using methods approved by the Director, Valley Region.
- e. Equipment in vacuum service is excluded from the requirements of this condition.
- f. Equipment in ethylene glycol service is excluded from the requirements of this condition.

(9 VAC 5-80-110)

- 6. Leak Definition for Organic HAPs – The instrument reading that defines a leak during organic HAP leak detection is:
 - a. Greater than or equal to 10,000 ppm for agitators, or
 - b. Greater than or equal to 2,000 ppm for pumps, or
 - c. Greater than or equal to 500 ppm for compressors, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems.

(9 VAC 5-80-110)

- 7. Leak Detection Equipment for Organic HAPs – Organic HAP leak detection equipment shall be operated in accordance with the following conditions:
 - a. Detection instrument performance criteria.
 - (1) Except as provided in (2) below, the detection instrument shall meet the performance criteria of Method 21 of 40 CFR part 60, appendix A, except the instrument response factor criteria in section 3.1.2(a) of Method 21 shall be for the average composition of the process fluid not each individual HAP in the stream. For process streams that contain nitrogen, air, or other inerts which are not organic HAP, the average stream response factor shall be calculated on an inert-free basis.
 - (2) If no instrument is available at the plant site that will meet the performance criteria specified in (1) above, the instrument readings may be adjusted by multiplying by the average response factor of the process fluid, calculated on an inert-free basis as described in (1) above.

- b. The detection instrument shall be calibrated before use on each day of its use by the procedures specified in Method 21 of 40 CFR part 60, appendix A.
- c. Calibration gases shall be as follows:
 - (1) Zero air (less than 10 parts per million hydrocarbon in air); and
 - (2) Mixtures of methane in air at a concentration less than 10,000 parts per million. A calibration gas other than methane in air may be used if the instrument does not respond to methane or if the instrument does not meet the performance criteria specified in (1) above. In such cases, the calibration gas may be a mixture of one or more of the compounds to be measured in air.
- d. An owner or operator may elect to adjust or not adjust instrument readings for background. If an owner or operator elects to not adjust readings for background, all such instrument readings shall be compared directly to the applicable leak definition to determine whether there is a leak. If an owner or operator elects to adjust instrument readings for background, the owner or operator shall measure background concentration. The owner or operator shall subtract background reading from the maximum concentration indicated by the instrument.
- e. The background level shall be determined according to the procedures in Method 21 of 40 CFR part 60 appendix A.

(9 VAC 5-80-110)

- 8. Leak Repair – The permittee shall repair any detected leaks, as indicated by the methods described in Conditions IV.B.3 – 7 or by visual, audible, or olfactory means, as soon as practicable, except as provided in Condition IV.B.9 below:
 - a. A first attempt at repair shall be made no later than 5 in-service calendar days after the leak is detected.
 - b. Repair shall be completed no later than 15 in-service calendar days after the leak is detected, except as provided in Condition IV.B.9 below.

(9 VAC 5-80-110)

- 9. Delay of Repair – Delay of repair of equipment for which leaks have been detected is allowed if one of the following conditions exist:

- a. The repair is technically infeasible without a process shutdown. Repair of this equipment shall occur by the end of the next scheduled process shutdown.
- b. The owner or operator determines that repair personnel would be exposed to an immediate danger if attempting to repair without a process shutdown. Repair of this equipment shall occur by the end of the next scheduled process shutdown.
- c. Equipment leaks have been detected but the equipment associated with the leak is isolated from the process and does not remain in HAP service,

(9 VAC 5-80-110)

10. Unsafe to Monitor – Equipment that is unsafe to monitor is exempt from the monitoring requirements of Conditions IV.B.3 and IV.B.5 if the permittee meets the requirements below:

- a. Equipment may be designated as unsafe to monitor if the permittee determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements in Conditions IV.B.3 and IV.B.5.
- b. The permittee has a written plan that requires monitoring of the equipment as frequently as practicable during safe-to-monitor times.

(9 VAC 5-80-110)

11. Difficult to Monitor – Equipment that is difficult to monitor is exempt from the monitoring requirements of Conditions IV.B.3 and IV.B.5 if the permittee meets the requirements below:

- a. The permittee determines that the equipment cannot be monitored without elevating the inspecting personnel more than 2 meters above a support surface; and
- b. The permittee has a written plan that requires inspection of the equipment at least once every 5 years.

(9 VAC 5-80-110)

12. Organic HAP Service – “In organic HAP service” means that a piece of equipment either contains or contacts a process fluid (liquid or gas) that is at least 5 percent, by weight, total organic HAPs.
(9 VAC 5-80-110)
13. aHCl Service - “In aHCl service” means that a piece of equipment either contains or contacts process aHCl (gas) that is at least five percent, by weight, aHCl.
(9 VAC 5-80-110)
14. Emission Factor Adjustment – The following provisions shall govern adjustments to emission factors for HCl and/or organic HAP equipment/equipment components:
 - a. If, at the completion of a monitoring cycle, the permittee determines that the emission factors are less than the emission factors developed according to the most recent monitoring cycle, the permittee may adjust the emission factors and the rolling annual emissions calculations to reflect the decreased emission factors for the 12-month period preceding completion of the most recent monitoring cycle upon approval of the DEQ. The adjusted emission factors may be used until the next monitoring cycle to quantify emissions from equipment/equipment components in HAP service.
 - b. If, at the completion of a monitoring cycle, the permittee determines that the emission factors are greater than the emission factors developed according to the most recent monitoring cycle, the rolling annual emissions calculations shall be adjusted to reflect the increased emission factors for the 12-month period preceding completion of the most recent monitoring cycle. If the permittee provides justification for use of an alternate date to which emissions calculations should be adjusted to account for identified leaks, the adjustment may be made to that date instead of for the preceding 12-month period. Justification shall include such information as documentation of date and cause of leak, person reporting leak, and actions taken to repair the leak. The adjusted emission factors shall be used until the next monitoring cycle to quantify emissions from equipment/equipment components in HAP service.
(9 VAC 5-80-110)
15. Leak Emission Calculations – - To demonstrate compliance with Condition IV. A.1, the permittee shall utilize the most recently developed emission factors, adjusted as appropriate according to Condition IV.B.14.
(9 VAC 5-80-110)
16. Emission Quantification – Abnormal Discharges –The permittee shall quantify HAP emissions resulting from abnormal discharges. Such events shall include, but not be limited to, rupture of storage tanks, vessels, or piping, valve or

coupling failure, industrial accidents, spills, etc. The quantification shall, to the extent possible, consider the magnitude and duration of the discharge and shall be included in the rolling monthly emissions calculations for individual and total HAPs. A log shall be kept documenting the occurrence and duration of such events, the resulting HAP emissions, and corrective action taken.

(9 VAC 5-80-110)

17. Wastewater Conveyance Systems Containing HAPs –The permittee shall quantify individual and total annual HAP emissions from open wastewater transfer points in each process area as a rolling monthly total. The quantification shall be based on engineering assessment and actual production conditions (wastewater flow rate, HAP concentration, etc.) for each month. Upon fulfillment of Condition VIII.B.2, the permittee shall no longer be required to calculate emissions of HAPs from wastewater conveyance systems.

(9 VAC 5-80-110)

18. Control Devices-less than one ton per year feed stream - For control devices that control vent streams totaling less than 1 ton/yr HAP emissions (either individually or in the aggregate), before control, and for which control credit is taken in HAP emissions calculations, monitoring shall consist of a daily verification that the device is operating properly during any period in which the control device is functioning in achieving the HAP removal used in emission calculations. If the control device is used to control batch process vents alone or in combination with other streams, the verification may be on a per batch basis. This verification shall include, but not be limited to, a daily or per batch demonstration that the unit is working as designed and may include the daily measurements of the parameters described in Conditions IV.B.20 through IV.B.24.

(9 VAC 5-80-110)

19. Control Devices-one ton per year or greater feed stream - For each control device that controls vent streams containing equal to or greater than one ton per year HAPs (either individual or in the aggregate), before controls, and for which control credit is taken in calculating HAP emissions, the permittee shall install and operate monitoring devices to allow tracking of operation within the established parameter levels. Monitoring parameters are specified for control scenarios in Conditions IV.B.20 through IV.B.24.

(9 VAC 5-80-110)

20. Scrubbers - For each scrubber controlling vent streams containing equal to or greater than one ton per year HAP (either individually or in the aggregate), before control, and for which control credit is taken in calculating HAP emissions, the permittee shall establish a minimum scrubber liquid flow rate or pressure drop as a site-specific operating parameter which must be measured and recorded every 15 minutes during the period in which the scrubber is functioning in achieving the HAP removal used in emissions calculations. If the scrubber uses a caustic

solution to remove acid emissions, the permittee shall establish a minimum pH of the effluent scrubber liquid as a site-specific operating parameter which must be monitored at least once a day during the period in which the scrubber is functioning in achieving the HAP removal used in emissions calculations. The minimum scrubber flowrate or pressure drop shall be based on the conditions anticipated under worst-case conditions.

- a. The monitoring device used to determine the pressure drop shall be certified by the manufacturer to be accurate to within a gage pressure of ± 10 percent of the maximum pressure drop measured.
- b. The monitoring device used for measurement of scrubber liquid flowrate shall be certified by the manufacturer to be accurate within ± 10 percent of the design scrubber liquid flowrate.
- c. The monitoring device shall be calibrated according to the monitoring device manufacturer's recommended calibration frequency or every two years, whichever is more stringent.

(9 VAC 5-80-110)

21. Condensers - For each condenser controlling vent streams containing equal to or greater than one ton per year HAP (either individually or in the aggregate), before control, and for which control credit is taken in calculating HAP emissions, the permittee shall establish the maximum condenser outlet gas temperature or the maximum condenser inlet coolant temperature or the maximum condenser outlet coolant temperature as a site-specific operating parameter which must be measured and recorded at least every 15 minutes during the period in which the condenser is functioning in achieving the HAP removal used in calculating emissions.

- a. The temperature monitoring device must be accurate to within ± 2 percent of the temperature measured in degrees Celsius or ± 2.5 °C, whichever is greater.
- b. The temperature monitoring device must be calibrated according to the monitoring device manufacturer's recommended calibration frequency or every two years, whichever is more stringent.

(9 VAC 5-80-110)

22. Thermal oxidizers - For each thermal oxidizer controlling vent streams containing equal to or greater than one ton per year HAP (either individually or in the aggregate), before control, and for which control credit is taken in calculating HAP emissions, the permittee shall establish the minimum temperature of the

gases exiting the combustion chamber as the site-specific operating parameter which must be measured and recorded at least once every 15 minutes during the period in which the combustion device is functioning in achieving the HAP removal used in emissions calculations.

- a. The temperature monitoring device must be accurate to within ± 0.75 percent of the temperature measured in degrees Celsius or ± 2.5 °C, whichever is greater.
- b. The monitoring device must be calibrated according to the monitoring device manufacturer's recommended calibration frequency or every two years, whichever is more stringent.

(9 VAC 5-80-110)

23. Carbon adsorbers (nonregenerative) – For each carbon adsorber controlling vent streams containing equal to or greater than one ton per year HAP (either individually or in the aggregate), before control, and for which control credit is taken in calculating HAP emissions, the permittee shall establish the operating time between replacement of the carbon adsorption media, based on worst-case conditions anticipated for the adsorber. The operating time since the last replacement of media shall be monitored and recorded.

(9 VAC 5-80-110)

24. Carbon adsorbers (regenerative) – For each carbon adsorber controlling vent streams containing equal to or greater than one ton per year HAP (either individually or in the aggregate), before control, and for which control credit is taken in calculating HAP emissions, the permittee shall monitor and record once per regeneration cycle the following parameters: 1) total regeneration stream mass or volumetric flow during the carbon bed regeneration cycle(s), 2) temperature of carbon bed after regeneration, 3) temperature of carbon bed within 15 minutes of completing any cooling cycles, 4) operating time since the end of last regeneration. A check for bed poisoning shall be conducted yearly.

- a. The temperature monitoring device must be accurate to within ± 0.75 percent of the temperature measured in degrees Celsius or ± 2.5 °C, whichever is greater.
- b. The monitoring device used for measurement of stream flow shall be certified by the manufacturer to be accurate within ± 10 percent of the design stream flowrate.

- c. The monitoring devices must be calibrated according to the monitoring device manufacturer's recommended calibration frequency or every two years, whichever is more stringent.

(9 VAC 5-80-110)

25. Alternative Monitoring - As an alternative to the parameters specified in Conditions IV.B.20 through IV.B.24, the permittee may monitor and record the outlet HAP concentration or both the outlet total organic compound concentration and outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the control device is functioning and the outlet concentration shall be used in calculating HAP emissions. The permittee need not monitor the hydrogen halide and halogen concentration if, based on process knowledge, the owner or operator determines that the emission stream does not contain hydrogen halides or halogens.

(9 VAC 5-80-110)

26. Averaging Periods - Averaging periods for parametric monitoring levels shall be established according to (a) through (c) below.

- a. Except as provided in (c), a daily (24-hour) or block average shall be calculated as the average of all values for a monitored parameter level set according to the procedures in Conditions IV.B.27 and IV.B.28 recorded during the operating day or block.
- b. The daily average may be from midnight to midnight or another continuous 24-hour period. The block average is limited to a period of time that is, at a maximum, equal to the time from the beginning to end of a batch process.
- c. Monitoring values taken during periods in which the control devices are not functioning in controlling HAP emissions, as indicated by periods of no flow, shall not be considered in the averages. Where flow to the device could be intermittent, the owner or operator shall install, calibrate and operate a flow indicator at the inlet or outlet of the control device to identify periods of no flow or shall maintain documentation indicating time periods when HAPs are not being vented to the control device.

(9 VAC 5-80-110)

27. Parameter Establishment without Testing - For HAP control devices for which a performance test is not required by Condition IV.D.1 and for which control credit is taken in calculating HAP emissions, the parametric levels shall be set based on manufacturer's recommendations or an engineering assessment for control of HAP constituents under worst-case conditions expected for the control device. Compound-specific control efficiencies for individual HAPs corresponding to the

chosen parameter levels may be established for a given control device based on manufacturer's recommendations or engineering assessment.

(9 VAC 5-80-110)

28. Parameter Establishment with Testing - For control devices for which a performance test is required by Condition IV.D.1, the parameter level must be established as follows:

- a. If the operating parameter level to be established is a minimum or maximum, it must be based on the average of the values from each of the three test runs.
- b. The owner or operator may establish the parametric monitoring level(s) based on the performance test supplemented by engineering assessments and manufacturer's recommendations. Performance testing is not required to be conducted over the entire range of expected parameter values. The rationale for the specific level for each parameter, including any data and calculations used to develop the level(s) and a description of why the level indicates proper operation of the control device shall be provided in the report of test results submitted to the Director, Valley Region, required by Condition IV.D.1.
- c. In determining parametric monitoring levels, the permittee shall perform intermediate calculations using at least three significant figures. However, the permittee may round the resultant parameter values to two significant figures in establishing appropriate values.

(9 VAC 5-80-110)

29. Parameters for Control Devices Controlling Batch Process Vents. For devices controlling batch process vents alone or in combination with other streams, the parameter level(s) shall be established in accordance with (a) and (b) below:

- a. If more than one batch emission episode has been selected to be controlled, a single level for the batch process(es) shall be determined from the initial compliance demonstration.
- b. Instead of establishing a single level for the batch process(es), as described in (a) above, the permittee may establish separate levels for each batch emission episode, selected to be controlled. If separate monitoring levels are established, the permittee shall provide a record indicating at what point in the daily schedule or log of processes the parameter being monitored changes levels and must record at least one reading of the new parameter level, even if the duration of monitoring for the new parameter is less than 15-minutes.

(9 VAC 5-80-110)

30. Request Approval to Monitor Alternative Parameters. The permittee may request approval to monitor parameters other than those required by Conditions IV.B.20 through IV.B.24. The request shall be submitted in writing to the Director, Valley Region. The alternative monitoring shall not be implemented prior to receiving approval from the Director, Valley Region.

(9 VAC 5-80-110)

31. Exceedances of Operating Parameters. For each control device treating vent streams containing equal to or greater than one ton per year HAPs (either individually or in the aggregate), before controls, and for which control credit is taken in calculating HAP emissions, the permittee shall record the occurrence and duration of periods of operating parameter exceedances. HAP emission factors and/or calculations used to show compliance shall be adjusted to reflect such exceedance periods. An exceedance of an operating parameter is defined as one of the following:

- a. If the parameter, averaged over the operating day or block, is below a minimum value established during the initial performance test (supplemented as appropriate by engineering assessment or manufacturer's recommendation), or, prior to testing, by engineering assessment or manufacturer's recommendations.
- b. If the parameter, averaged over the operating day or block, is above the maximum value established during the initial performance test (supplemented as appropriate by engineering assessment or manufacturer's recommendation), or, prior to testing, by engineering assessment or manufacturer's recommendations.
- c. It shall not be considered an exceedance, and emission factors shall not be adjusted to reflect the exceedance, if the exceedance occurs during a time when HAPs are not being vented to the control device.

Exceedances of operating parameters occurring during a startup, shutdown, or malfunction do not constitute a violation of this permit provided HAP emission factors and/or calculations used to show compliance are adjusted to reflect such exceedance periods in accordance with this condition.

(9 VAC 5-80-110)

32. Excursions. For each control device treating vent streams containing equal to or greater than one ton per year HAPs (either individually or in the aggregate), before controls, and for which control credit is taken in calculating HAP emissions, the permittee shall record the occurrence and duration of periods of operating parameter excursions. HAP emission factors and/or calculations shall be adjusted to reflect such excursion periods. Excursions are defined by either of the two cases listed in (a) or (b) below:

- a. When the period of control device operation is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data for at least 75 percent of the operating hours.
- b. When the period of control device operation is less than 4 hours in an operating day and more than one of the hours during the period of operation does not constitute a valid hour of data due to insufficient monitoring data.
- c. Monitoring data are insufficient to constitute a valid hour of data, as used in (a) and (b), if measured values are unavailable for any of the required 15-minute periods within the hour.
- d. It shall not be considered an excursion, and emission factors shall not be adjusted to reflect the excursion, if the excursion occurs during a time when HAPs are not being vented to the control device.

As an alternative to adjusting HAP emission factors and/or calculations to reflect an excursion, the permittee may provide verification and documentation through independent means sufficient to establish that the control device was operating properly during the period that the monitoring system failed to collect data.

Operating parameter excursions occurring during startup, shutdown, or malfunction do not constitute a violation of this permit provided HAP emission factors and/or calculations used to show compliance are adjusted to reflect such excursion periods in accordance with this condition.

(9 VAC 5-80-110)

33. *Inspection and Monitoring of Waste Management Units and Treatment Processes*

For each wastewater tank, container, and individual drain system that receives, manages, or treats wastewater, a residual removed from wastewater, a recycled wastewater, or a recycled residual removed from wastewater, the permittee shall comply with the inspection requirements, as applicable, specified in Table V below.

Table V. Inspection and monitoring requirements for waste management units

Unit	Inspection or monitoring requirement	Frequency of inspection or monitoring	Method
Tanks	Inspect fixed roof and all openings for leaks, as applicable	Semiannually	Visual
	Inspect floating roof seal primary and secondary gaps, as applicable		
	Inspect wastewater tank for control equipment failures and improper work practices, as applicable		
	Inspect surface impoundment for control equipment failures and improper work practices, as applicable		
Containers having volume $\geq 0.1 \text{ m}^3$	Inspect cover and all openings for leaks, as applicable	Semiannually	Visual
	Inspect enclosure and all openings for leaks, as applicable		
	Inspect container for control equipment failures and improper work practices, as applicable		
Individual drain systems	Inspect cover and all openings to ensure there are no gaps, cracks, or holes, as applicable	Semiannually	Visual
	Inspect individual drain system for control equipment failures and improper work practices, as applicable		
	Verify that sufficient water is there to properly maintain integrity of water seals, as applicable		
	Inspect all drains using tightly fitted caps or plugs to ensure caps and plugs are in place and properly installed, as applicable		
	Inspect all junction boxes to ensure covers are in place and have no visible gaps, cracks, or holes, as applicable		
	Inspect unburied portion of all sewer lines for cracks and gaps, as applicable		

34. Emissions calculations - To show compliance with the limits in Condition IV.A.1, when HAP input values are based on Material Safety Data Sheets (MSDS) and the MSDS shows a HAP content as a range, the maximum range value shall be used in emission calculations.

(9 VAC 5-80-110)

35. Wastewater treatment plant (WWTP) emission calculations – If actual sitewide HAP emissions are greater than or equal to 90% of the allowable sitewide HAP emissions in Condition IV.A.1, the permittee shall, upon the request of DEQ, calculate WWTP emissions for pre-aeration operations using the latest version of the WATER9 predictive model or shall conduct testing to verify TOXCHEM results.

(9 VAC 5-80-110)

C. Recordkeeping

The permittee shall maintain records of all emission data and operating parameters necessary to demonstrate compliance with this permit. The content and format of such records shall be arranged with the Director, Valley Region. These records shall include, but are not limited to:

1. HAP emission factors used to calculate individual and total HAP emissions for each manufacturing process at the facility. Such emission factors shall be expressed as pounds of individual and total HAP emissions per production unit for each HAP-emitting manufacturing process at the facility. Adjustments to emission factors to reflect periods of control device parameter exceedances or excursions or periods during which the control device was not operated due to malfunction shall also be recorded for all periods during which HAPs are vented to the control devices.
2. Records of operational parameter monitoring for Carbidopa process control devices/practices as specified in Condition VIII.B.1.
3. Site-specific emission factors for equipment/equipment components. Adjustments to equipment emission factors according to Condition IV.B.14 shall be recorded.
4. Leaks not repaired within the time frames specified in Condition IV.B.8 shall be recorded.
5. Records of abnormal discharges as required in Condition IV.B.16.
6. Number of production units per month and year for each HAP-emitting manufacturing process at the facility.
7. Monthly and annual calculations of individual and total HAP emissions resulting from all manufacturing processes at the facility (including Central Solvent Recovery). Annual emissions shall be calculated monthly as specified in

Condition IV.A.1 for sitewide emissions. Calculations of emissions during periods of control device parameter exceedance and excursions or periods during which the control device was not operated due to malfunction at times when HAPs are vented shall be based on control equipment operation at the parametric values recorded during such exceedance or excursion periods or on uncontrolled emission factors.

8. Monthly and annual calculations of individual and total HAP emissions resulting from equipment/equipment components. Annual emissions shall be calculated monthly as specified in Condition IV.A.1 for sitewide emissions. Emissions calculations shall be adjusted according to Condition IV.14.
9. Monthly and annual calculations of individual and total HAP emissions resulting from wastewater treatment. Calculations shall be based on TOXCHEM modeling utilizing measured data for influent flow, influent temperature, and monthly average values for influent HAP concentrations. Annual emissions shall be calculated monthly as specified in Condition IV.A.1.
10. Monthly and annual calculations of individual and total HAPs from miscellaneous sources, to include, but not limited to, sludge drying, wastewater conveyance systems (according to Condition IV.B.17), abnormal discharges (according to Condition IV.B.16), stationary internal combustion engines, fugitives (e.g., cooling water towers and drum washing activities), lab hoods (using the site-specific emission factor(s) developed for methanol according to Item 6, Appendix A, July 8, 2005 Consent Order between Merck & Co., Inc. and DEQ), boilers, gasoline tanks, and materials used in maintenance, repair, and construction activities (coatings, adhesives, lubricants, etc.). Annual emissions shall be calculated monthly as specified in Condition IV.A.1 for sitewide emissions.
11. Production/operating characteristics (wastewater flow rate, HAP concentration, etc.) used as input values for process-area wastewater conveyance emissions calculations.
12. Material Safety Data Sheets (MSDS) for all HAP-containing raw materials received from third-party vendors and suppliers and used as feedstock to pharmaceutical production processes.
13. Calibrations of wastewater influent concentration analyzer(s) and flow meter(s).
14. The occurrence and duration of each period during which a control device for which control credit is taken in calculating HAP emissions was not operated.

15. The occurrence and duration of each malfunction of continuous monitoring systems used on air pollution control equipment for which control credit is taken in calculating HAP emissions.
16. Manufacturer's recommendation or engineering assessment showing control device parameters corresponding to proper operation as determined according to Condition IV.B.27.
17. Performance test results showing control device parameters corresponding to proper operation as determined according to Condition IV.B.28.
18. Daily verification of proper control device operation (in accordance with Condition IV.B.18), each measurement of a control device operating parameter monitored (in accordance with Conditions IV.B.20 through IV.B.24.), and, as applicable, outlet HAP concentration or outlet total organic compound concentration (in accordance with Condition IV.B.25).
19. For each continuous monitoring system used on air pollution control equipment for which control credit is taken in calculating HAP emissions, records documenting the completion of calibration checks and maintenance of continuous monitoring systems.
20. All maintenance performed on the air pollution control equipment for which control credit is taken in calculating HAP emissions.
21. For each control device listed in Condition IV.A.2 and Table IV, a record documenting periods, lasting more than one hour, during which the control device is not operating and the passing vent stream contains HAPs and records of the durations of periods of flow through bypass routes as specified in Condition IV.B.1.
22. A record that each waste management unit inspection required by Condition IV.B.33 and Table V was performed, as applicable.
23. Records of initial and subsequent leak detection inspections performed in accordance with Conditions IV.B.3 and IV.B.5.
24. For each inspection conducted in accordance with Conditions IV.B.3 and IV.B.5 during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected.
25. For each inspection conducted in accordance with Conditions IV.B.3 and IV.B.5 during which a leak is detected, a record of the following information:
 - a. Identification of the leaking equipment.

- b. The instrument identification numbers and operator name or initials, if the leak was detected using methods specified in Conditions IV.B.3 and IV.B.5, or a record that the leak was detected by sensory observations.
 - c. The date the leak was detected and the date of the first attempt to repair the leak.
 - d. Maximum instrument reading measured by the methods specified in Conditions IV.B.3 and IV.B.5 after the leak is successfully repaired or determined to be nonrepairable.
 - e. "Repair delayed" and the reason for the delay if a leak is not repaired within 15 in-service calendar days after discovery of the leak (according to Condition IV.B.8).
 - f. The expected date of successful repair of the leak if a leak is not repaired within 15 in-service calendar days.
 - g. The date of successful repair of the leak.
26. List of all equipment designated as "unsafe to monitor" and the reason for such designation (according to Condition IV.B.10).
27. List of all equipment designated "difficult to monitor", the reason for such designation, and the written plan specifying periodic inspections (according to Condition IV.B.11).
28. Lists/records documenting equipment not meeting the definition of "in organic HAP service" or "in aHCl service" (according to Conditions IV.B.12 and IV.B.13).
29. For each nonregenerative carbon adsorber, operating time elapsed between replacement of adsorption media.
30. For each regenerative carbon adsorber, values of parameters identified in Condition IV.B.24, at least once per regeneration cycle.

These records shall be available on site for inspection by the DEQ and shall be current for the most recent five years.

(9 VAC 5-80-110)

D. Testing

- 1. Within 180 days of either (1) installation of a new or replacement control device treating a gas stream containing equal to or greater than five tons per year HAPs (either individually or in the aggregate) or (2) beginning to take HAP control credit in calculating emissions for a unit controlling equal to or greater than five

tons per year HAPs (either individually or in the aggregate) for which no control credit was previously taken, the permittee shall conduct performance testing according to EPA reference methods to determine the control efficiency of the device for the HAP comprising the highest concentration in the stream. Control efficiencies of each control device for additional HAPs may be determined using EPA reference methods and used in subsequent calculations. This requirement may be waived for a control device if the device was tested within the most recent five years, upon approval of such waiver by DEQ. Testing shall be conducted under conditions which are most challenging for the control device; such conditions may be maximum pollutant loading to the device or other loading scenarios reasonably expected to occur that may be more challenging to the unit than maximum load. Test results, supplemented as appropriate by engineering assessment or manufacturer's recommendations, shall be used to determine appropriate control device operating parameters necessary to achieve maximum control efficiency.

(9 VAC 5-80-110)

2. If testing is conducted in addition to the monitoring specified in this permit, the permittee shall use the following test methods in accordance with procedures approved by the DEQ as follows:

Pollutant	Test Method (40 CFR Part 60, Appendix A)
Volatile HAP	EPA Method 25
Hydrogen chloride/Hydrochloric acid	EPA Method 26/26A
Volatile HAP leak detection	EPA Method 21

(9 VAC 5-80-110)

E. Reporting

1. For each quarterly period ending March 31, June 30, September 30, and December 31, beginning November 1, 2003, the permittee shall report to the Director, Valley Region, the rolling 12-month total HAP emissions (individual and in the aggregate) as of the end of each quarter.
2. Reports shall be submitted no later than 60 days after the end of each quarter.

(9 VAC 5-80-110)

3. The permittee shall furnish written notification to the Director, Valley Region, of shutdown or malfunctions lasting more than one hour of control equipment listed in Table IV (Condition IV.A.2) which result(s) in HAP emissions exceeding 10 pounds. The notification requirement is waived if the treated stream does not contain HAPs or, if it does contain HAPs, the stream is routed to an alternative equivalent control device or the process generating the emission stream is shut down within one hour pending the return to normal operation of the control device. During such shutdown or malfunction periods, a log shall be maintained

documenting the expected presence of HAPs in the vent stream and any equivalent alternative control device receiving the stream. The permittee shall provide a written statement giving all pertinent facts, including the duration of the breakdown, the HAP emissions resulting from the downtime and the emission factor adjustment, within 14 days of the occurrence.

(9 VAC 5-80-110)

4. The permittee shall furnish notification to the Director, Valley Region, of significant modifications and significant new installations.
 - a. Significant modifications for the purposes of this section are defined as changes to an existing process unit that result in an increase of the potential emissions of the process unit after consideration of existing controls of more than any of the significance levels listed in Condition IV.E.4.b(1). Significant new installations for the purposes of this section are defined as new process units with potential emissions before controls that exceed either of the significance levels in Condition IV.E.4.b(2). For purposes of this section, potential emissions means process unit point source emissions that would be generated by the process unit operating at its maximum capacity.
 - b. Significance levels for determining significant modifications and significant new installations:
 - (1) Significant modifications
 - (a) An increase in emissions of any individual HAP greater than or equal to one ton/year;
 - (b) An increase in emissions of total HAPs greater than or equal to 2.5 tons/year;
 - (c) Emissions of an individual HAP not previously emitted by the process unit greater than or equal to one ton/year.
 - (2) Significant new installations
 - (a) Emissions of any individual HAP greater than or equal to one ton/year;
 - (b) Emissions of total HAPs greater than or equal to 2.5 tons/year.
 - c. The notification shall be in writing and shall be submitted within 45 days of the commencement of operation. The notification shall include the following information:
 - (1) A description of the new or modified equipment, to include a schematic diagram showing the type and sequence of equipment installed or

modified, equipment identification numbers, location of the new installation or modification on the plant site;

(2) Air pollution control equipment associated with the new installation or modification;

(3) The total emissions of each HAP emitted from each piece of new or modified equipment (before and after controls);

(4) Changes in emission factors for each HAP emitted (expressed as lbs HAP per production unit) resulting from the new installation or modification; and

(5) For modifications, a statement addressing the effect that the modification will have on the performance of existing air pollution control equipment.

(9 VAC 5-80-110)

V. Facility-Wide Conditions for Hazardous Air Pollutants – Major Source Operation

The permittee shall become a major source for hazardous air pollutants (HAPs) on January 1, 2008 and shall comply with all applicable provisions of 40 CFR 63 Subpart GGG (National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production) and the initial notification requirement of 40 CFR 63 Subpart DDDDD (NESHAP for Industrial, Commercial and Institutional Boilers). The permittee may delay becoming a major source for HAPs by submitting to the Director, Valley Region, an “opt-out” notification at least thirty (30) days prior to that date. Such notification shall include a statement that the site will not become a major HAP source and will continue to operate as a minor HAP source under the terms of Section IV of the Title V operating permit. Such notification shall constitute a continuance of the transition date for a period of six (6) calendar months and may be repeated at six month intervals for the duration of the 5 year Title V permit renewal period, subject to the thirty (30) day “opt-out” notice.

On the date the facility becomes a major source of HAPs, the permittee will become subject to the following applicable provisions of 40 CFR 63 Subpart GGG (codified in Attachment B) and the initial notification requirement of 40 CFR 63 Subpart DDDDD, which shall supersede the limits, monitoring, recordkeeping and reporting requirements otherwise effective for HAPs in Section IV of this permit.

A. Limitations

1. The permittee shall comply with the emission standards for process vents, storage tanks, equipment leaks and wastewater in Subpart GGG – National Emission Standards for Pharmaceutical Production, 40 CFR Part 63 Sections 1253 – 1256 (which includes the emission standards and limitations detailed in Attachment B). The process operations subject to these standards include: Carbidopa, Indinavir, MK-476, Central Solvent Recovery, Cilastatin, Imipenem, Sodium Bicarbonate, Primaxin for Recovery, MK-991, Dorzolamide and wastewater treatment correlated with Unit Reference Numbers 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23, and F, respectively.
(9 VAC 5-80-110)
2. Change Control
 - a. The permittee shall be able to make changes as described in Condition V.A.2.b and V.A.2.c pursuant to 40 CFR 63 Subpart GGG without a revision to this permit if the permittee follows the procedures established in the table below and records the information in the on-site implementation log as required in Condition V.A.2.d.

REPLICABLE PROCEDURES AS WRITTEN IN SUBPART GGG

Procedure	40 CFR Part 63 Citation
Calculating uncontrolled emissions from process vents--equations for eight types of operations	63.1257(d)(2)(i)(A) through (H)
Calculating controlled emissions from process vents discharged through a condenser--equations for eight types of operations	63.1257(d)(3)(i)(B)(I) through (8)
Equations for determining whether an existing vent is subject to 98% control	63.1254(a)(3)(i)
Maximum true vapor pressure for determining storage tank applicability.	63.1251 definition
EPA performance test methods and calculations	63.1257(a)(2), (a) (3), (b)(1) through (8), and (b)(10)(i) through (iii)

- b. The permittee may make changes to existing process equipment to include shifting/reconfiguring process equipment and eliminating process equipment provided that the new configuration does not exceed the worst-case operating conditions of the control devices as demonstrated in the Notification of Compliance Status Report (NOCSR) required by 40 CFR 63.1260(f) and that the new configuration complies with all applicable requirements under 40 CFR 63 Subpart GGG.
- c. New equipment added to existing process configurations shall be limited to the following:
 - (1) New control devices that may be added under Condition V.A.2 are limited to new condensers that are like-kind replacements for those currently incorporated into the permit through the NOCSR;
 - (2) New process equipment added under Condition V.A.2 is limited to:
 - (a) Like-kind replacement of permitted process equipment that is being retired, where the replacement equipment is functionally equivalent to and provides no greater production capacity than the equipment being retired. New process equipment that is replacing equipment that will continue in service elsewhere at the site may not be added under Condition V.A.2;

- (b) Process equipment which already exists on-site but is not in current service. Such equipment shall be specifically identified in the permit in terms of its type and capacity.
- (c) For both Conditions V.A.2.c(2)(a) and (b), the additions of such equipment shall meet all provisions of the permit and of 40 CFR 63 Subpart GGG governing its operation, including the requirement to stay within the approved performance capabilities or capacity limitations (based on the NOCSR) of the control device to which its emissions are routed.
- d. The permittee shall maintain an on-site implementation log (OSIL) and associated records on and after the date on which the source becomes a major source for HAPs and becomes subject to 40 CFR 63 Subpart GGG to document all process changes and to document the current operating scenario for each process in operation at the facility. Failure to maintain the OSIL and associated records, failure to revise the OSIL each time any process's operating scenario changes, and failure to operate according to the compliance obligations established in the OSIL are violations of this permit and of the underlying requirement. The operating scenario included in the OSIL for each process must include the following information:
 - (1) A description of the process and the type of process equipment used.
 - (2) An identification of related process vents and their associated emissions episodes and durations, wastewater points of determination (PODs), and tanks.
 - (3) The applicable control requirements of subpart GGG, including the level of required control.
 - (4) The control or treatment devices used, as applicable, including a description of operating and/or testing conditions for any associated control device.
 - (5) The process vents, wastewater PODs, and storage tanks (including those from other processes) that are simultaneously routed to the control or treatment device(s).
 - (6) The applicable monitoring requirements of subpart GGG and any parametric level that assures compliance for all emissions routed to the control or treatment device.
 - (7) Calculations and engineering analyses required to demonstrate compliance, including the basis for such calculations and analyses.

- (8) A verification that the operating conditions for any associated control or treatment device have not been exceeded and that any required calculations and engineering analyses have been performed.
- e. The permittee shall notify the Director, Valley Region, in writing within 30 days of any changes to the applicable requirements specified in Condition V.A.1 resulting from new or changed HAP sources (as allowed under Condition V.A.2) at the site.
- f. The permittee shall submit quarterly reports to DEQ of any new operating scenarios contained in the OSIL which occurred during the quarterly period, including (but not limited to) any process changes. For reporting purposes, a change to any of the elements listed above in Condition V.A.2.d above, except for element (v), that has not been included in any previous report shall constitute a new operating scenario. The quarterly reports must be submitted to the DEQ on or before 60 days after the end of the quarterly reporting period. The first report must be submitted no later than 180 days after the date that the source becomes a major source for HAPs and must include each operating scenario for each process operated during the period from the date the source first becomes subject to 40 CFR 63 Subpart GGG to the end of the first 6-month period after that date.
- g. Changes that implicate applicable requirements other than or in addition to 40 CFR 63 Subpart GGG shall be addressed in the manner required by 9 VAC 5 Chapter 80, Article 1.

(9 VAC 5-80-110)

B. Monitoring

The permittee shall meet all monitoring requirements for process vents, storage tanks, equipment leaks and wastewater in Subpart GGG – National Emission Standards for Pharmaceutical Production, 40 CFR Part 63 Section 1258 (which includes the monitoring requirements detailed in Attachment B).

(9 VAC 5-80-110)

C. Recordkeeping

- 1. The permittee in accordance with Subpart GGG – National Emission Standards for Pharmaceutical Production, 40 CFR Part 63 Section 1259 shall record and retain all information necessary to determine that the operation of the process vents, storage tanks, equipment leaks and wastewater system is in compliance with 40 CFR 63.1253 –1256 (which includes the recordkeeping requirements detailed in Attachment B).

(9 VAC 5-80-110)

2. At all times, the site shall maintain a current list of affected operating areas subject to the requirements in Conditions V.A.1, V.B, V.C.1, V.D, or V.E on site and available for inspection.

(9 VAC 5-80-110)

D. Reporting

1. The permittee in accordance with Subpart GGG – National Emission Standards for Pharmaceutical Production, 40 CFR Part 63 Section 1260 shall meet all applicable reporting requirements for process vents, storage tanks, equipment leaks and wastewater subject to 40 CFR Part 63 Sections 1253 – 1256 (which includes the reporting requirements detailed in Attachment B).
(9 VAC 5-80-110)
2. Within 120 calendar days of becoming a major HAP source, the permittee shall submit an Initial Notification for the NESHAP for Industrial, Commercial and Institutional Boilers (40 CFR 63 Subpart DDDDD) which provides the following information:
 - a. The name and address of the owner or operator;
 - b. The address (i.e., physical location) of the affected source;
 - c. An identification of the relevant standard, or other requirement, that is the basis of the notification and the source's compliance date;
 - d. A brief description of the nature, size, design, and method of operation of the source and an identification of the types of emission points within the affected source subject to the relevant standard and types of hazardous air pollutants emitted; and
 - e. A statement of whether the affected source is a major source or an area source.

(9 VAC 5-80-110, 40 CFR 63.7545(a) and 40 CFR 63.9(b)(2))

E. Testing

The permittee shall conduct all required testing in accordance with Subpart GGG – National Emission Standards for Pharmaceutical Production, 40 CFR Part 63 Section 1257 (which includes the testing requirements detailed in Attachment B). Previous testing of control devices conducted in accordance with procedures approved by the DEQ as a synthetic minor source for HAPs, but subsequently subject to 40 CFR 63.1257 as a major HAP source for HAPs, may meet these requirements upon case-by-case approval by the Director, Valley Region.

(9 VAC 5-80-110)

VI. Facility-Wide Conditions for Visible Emissions

A. Limitations

1. Visible emissions from each process unit stack constructed, reconstructed, or modified after March 17, 1972, shall not exceed 20% opacity as determined by EPA Method 9 (reference 40 CFR 60, Appendix A), except during one six-minute period in any one hour in which visible emissions shall not exceed 30% opacity. This condition applies at all times except during startup, shutdown or malfunction.
(9 VAC 5-50-80 and 9 VAC 5-80-110)
2. Visible emissions from each process unit stack constructed, reconstructed, or modified prior to March 17, 1972, shall not exceed 20% opacity as determined by EPA Method 9 (reference 40 CFR 60, Appendix A), except during one six-minute period in any one hour in which visible emissions shall not exceed 60% opacity.
(9 VAC 5-40-80 and 9 VAC 5-80-110)

B. Monitoring

1. The permittee shall install, calibrate, maintain, and operate a continuous monitoring and recording system on the natural gas-fired boilers for measuring opacity using a continuous emissions monitoring system or a predictive emissions monitoring system.
(9 VAC 5-80-110 and 40 CFR 60.49b(u)(1)(ii))
2. The permittee shall conduct visible emission inspections on each process unit stack in accordance with the following procedures and frequencies:
 - a. At a minimum of once per month, the permittee shall determine the presence of visible emissions. If during the inspection, visible emissions are observed, a visible emission evaluation (VEE) shall be conducted in accordance with 40 CFR 60, Appendix A, EPA Method 9, unless timely corrective action is taken such that the stack resumes operation with no visible emissions. The VEE shall be conducted for a minimum of six minutes. If any of the observations exceed 20%, the VEE shall be conducted for a total of 60 minutes.
 - b. All visible emissions inspections shall be performed when the process unit is operating.
 - c. If visible emissions inspections conducted during 12 consecutive months show no visible emissions for a particular process unit stack, the permittee may reduce the monitoring frequency to once per quarter for that process unit

stack. Anytime the quarterly visible emissions inspections show visible emissions, or when requested by DEQ, the monitoring frequency shall be increased to once per month for that stack.

- d. For process units that do not operate year round, 12 non-consecutive monthly visible inspections shall be performed. If visible emissions inspections conducted during 12 non-consecutive months show no visible emissions for a particular process unit stack, the permittee may reduce the monitoring frequency to once per quarter for that process unit stack. Anytime the quarterly visible emissions inspections show visible emissions, or when requested by DEQ, the monitoring frequency shall be increased to once per month for that stack.

All observations, VEE results, and corrective actions taken shall be recorded.
(9 VAC 5-80-110)

3. The requirement for visible emissions inspections shall not apply to the following emissions units:
 - a. Internal combustion engines used as emergency units and operated for less than five consecutive days.
 - b. Units for which continuous opacity monitoring is required by this permit.
 - c. Any process unit that has uncontrolled particulate matter or PM-10 emissions of less than five tons per year as listed in Attachment A of this permit. Attachment shall be updated without permit amendment in accordance with Condition VI.E.

(9 VAC 5-80-110)

C. Recordkeeping

The permittee shall maintain records of all emission data and operating parameters necessary to demonstrate compliance with this permit. The content and format of such records shall be arranged with the Director, Valley Region. These records shall include, but are not limited to:

1. Records of continuous opacity monitoring as required in Condition VI.B.1.
2. Records of visible emissions monitoring as required in Condition VI.B.2.
3. An up-to-date version of Attachment A.

These records shall be available on site for inspection by the DEQ and shall be current for the most recent five years.

(9 VAC 5-80-110)

D. Testing

If testing is conducted in addition to the monitoring specified in this permit, the permittee shall use the following test methods in accordance with procedures approved by the DEQ as follows:

Pollutant	Test Method (40 CFR Part 60, Appendix A)
Visible Emission	EPA Method 9

(9 VAC 5-80-110)

E. Reporting

The permittee shall notify the Director, Valley Region, in writing within 30 days of equipment or process changes resulting in increased particulate matter (PM) emissions for units listed in Attachment A, if the resulting uncontrolled PM emissions level for such a unit is greater than five tons per year. Following the equipment or process change, such equipment shall be subject to the visible emissions monitoring requirements in Condition VI.B.2. If an emissions unit not listed in Attachment A undergoes equipment or process changes resulting in an adjusted uncontrolled PM emissions level below five tons per year, the permittee shall notify the Director, Valley Region in writing before ceasing the visible emissions monitoring required by Condition VI.B.2. At all times, an up-to-date version of Attachment A shall be maintained on site and available for inspection.

(9 VAC 5-80-110)

VII. Administration Of PSD (Project XL) Permit

A. Periodic Review of the PSD Permit

The PSD permit shall be periodically reviewed as specified in this section. Changes to the PSD permit shall be made either: after full consent of the project signatories and subject to the permit modification procedures promulgated in the permittee's site-specific rule, or pursuant to PSD permit modification procedures generally applicable to all PSD permits. Changes to the PSD permit other than those described below are not subject to review except as otherwise agreed to by full consent of the project signatories. Discussion of issues brought by the project stakeholders relating to the PSD permit may occur as needed.

1. Five-Year Periodic Review

Within three months of the five year anniversary of the completion of the powerhouse conversion project (i.e., within three months of July 12, 2005) and every five years thereafter, the project stakeholders shall reconvene to review whether any of the following changes to the PSD permit are required.

- a. Significant changes in calculation methods – Current state-of-the-art emission estimation techniques are used to calculate emissions from the site. These methods and their application to the site's emission sources are specified in Table I. If significant changes are made to these methods, or new methods are identified that are determined to be appropriate for emission sources at the site, adjustments to the site's emissions caps, HEP and current actual emissions may be considered, depending on the nature and extent of the new methods or changes to the current emission estimation techniques.
- b. Change in list of criteria pollutants or National Ambient Air Quality Standards (NAAQS) – If EPA adds, deletes, or modifies the list of criteria pollutants or NAAQSs, adjustments to the site's emission caps, HEP, current actual emissions, and other changes to the PSD permit may be considered, depending on the reason for the change and its impact on the site's emission totals. If changes are made to incorporate the revision, Condition III.A.1 will also be revised to reflect the addition, deletion, or modification of the pollutant.
- c. Review of examples of control technology in Condition III.A.1.f.(2)(c) – Controls listed in Condition III.A.1.f.(2)(c) represent good environmental engineering practice with regard to controlling air pollutants. Changes to this list may be considered, including evaluation of new control technology, to ensure that the section continues to represent good environmental engineering practice.

- d. Adequacy of Condition III.B.2 requirements – Condition III.B.2 (Monitoring, Recordkeeping, and Reporting Requirements) may be reviewed to ensure that it provides information necessary to evaluate the site's performance under the agreement. This section also may be reviewed to identify overlapping or unnecessary requirements.
 - e. Review Procedure for New Criteria Pollutant Regulations – Condition III.A.1.e.(1)(c) describes the review and approval procedure for the emissions cap adjustment for new regulations. This procedure may be evaluated and changes to the procedure considered in order to facilitate timely and appropriate adjustments.
 - f. Review of Termination Criteria – Condition VII.C specifies criteria subject to which the PSD would be terminated. These criteria may be evaluated and changes considered as deemed necessary.
 - g. Review of Modeling for Short Term PM-10 and SO₂ emissions – Prior to the five-year review, the permittee shall submit to the project stakeholders information necessary to perform short term PM-10 and SO₂ NAAQS modeling, similar in extent and detail to the modeling performed for the original PSD permit support documentation. This information shall include but not be limited to the current plant configuration with information on building locations and dimensions, information on emission sources including stack dimensions, exit gas parameters, and emission rates for actual operating conditions and worst case short-term (3 and 24-hour) operating conditions. If major changes have been made at the site not reflected in the most recent modeling analysis, the permittee shall perform an updated modeling analysis if requested by EPA or VADEQ.
 - h. Review of the Determination that the Area is NO_x Limited for Ozone Formation – If any project stakeholders present technical papers or studies that change the generally recognized determination that the area near the site, including the Shenandoah National Park, is NO_x-limited for ozone formation, changes to terms of the PSD permit may be considered.
 - i. Review of Periodic Review Criteria – Condition VII.A specifies criteria by which the PSD permit shall be periodically reviewed. These criteria may be evaluated and changes considered as deemed necessary.
2. Review Triggered by Emission Levels
- a. Review of Air Quality Related Values (AQRVs)

- (1) Trigger for AQRV Assessment: The AQRV assessment specified in this subsection shall be triggered upon either of the following events:
- (a) After installation of any individual new process or process modification that results in a net increase in the site's actual VOC emissions of 100 TPY or more. Net increase means the sum of emission increases and decreases occurring at the site resulting from the new or modified installation.
 - (b) After the first time the site-wide VOC emissions exceed two times the baseline (Table VII) VOC level (i.e., if site-wide VOC emissions reach 816 TPY).

Table VII. Actual Criteria Pollutant Emissions from the Stonewall Site.

Pollutant	1992 Actual Emissions (TPY)	1993 Actual Emissions (TPY)	Average of 1992 and 1993 (TPY)	Emission Cap Established in Condition III.A.1.a.-d.
SO ₂	714	723	719	539
NO _x	293	290	291	262
CO	44	42	43	N/A
PM-10	42	42	42	46
VOC	442	374	408	N/A
Total Criteria Emissions	1535	1471	1503	1202

- (2) AQRV Assessment: If an AQRV assessment is triggered in VII.A.2.a.(1), VOC emission increases shall be reviewed to determine whether they are the cause of or significantly contribute to adverse impacts on any AQRVs at the Class I area (Shenandoah National Park). The permittee shall be responsible for performing the assessment of VOC impacts on AQRVs using demonstrated methods for such assessments.
- (3) Mitigation Measures: If the project signatories agree that the permittee's VOC emissions are the cause of adverse impacts on any AQRVs at the Class I area (Shenandoah National Park), the permittee shall implement mitigation measures that are agreed to by the project signatories.

- b. Review of Non-HAP VOCs – No later than three months after the site-wide VOC emissions reach 125% of the baseline (Table VII) VOC level (i.e., if site-wide VOC emissions reach 510 TPY):

- (1) The permittee shall provide to the project stakeholders the list of non-HAP VOCs that were emitted from the facility in the previous 12 months. EPA shall conduct a review of the scientific literature for any new information on the health effects of these compounds and provide such information to the project stakeholders.
- (2) The permittee shall conduct a site-wide modeling assessment of non-HAP VOC emissions yielding average property line concentrations. These modeling results shall be compared to the Significant Ambient Air Concentrations (SAAC) established in the Virginia Air Regulations (9 VAC 5 Chapter 60, Articles 4 and 5 (9 VAC 5-60-200 et seq. and 9 VAC 5-60-300 et seq.) (formerly 9 VAC 5 Chapter 40, Part II, Article 3 (9 VAC 5-40-160 et seq.) and 9 VAC 5 Chapter 50, Part II, Article 3 (9 VAC 5-50-160 et seq.)), except the most recent Threshold Limit Values published by the ACGIH shall be used in the SAAC calculations. If this assessment predicts an exceedance of the SAAC for any of the modeled substances, the permittee shall either:
 - (a) Demonstrate to the VADEQ's satisfaction that the applicable SAAC is inappropriate for the substance in question by showing that the emissions from the site produce no endangerment of human health; or
 - (b) Implement changes at the site resulting in ambient concentrations of the substance that are below the SAAC or resulting in such other ambient concentrations acceptable to the VADEQ.

Any actions pursuant to VII.A.2.b.(2)(a) or VII.A.2.b.(2)(b) to resolve any SAAC exceedance shall be initiated within four months of reaching the VOC level that triggered this subsection, and communicated to the project stakeholders.

- (3) Subsequent assessments specified in VII.A.2.b.(1) and VII.A.2.b.(2) shall be conducted if site-wide VOC emissions increase further whenever such incremental increases exceed 100 TPY (i.e., at VOC levels of 610 TPY, 710 TPY, 810 TPY, etc.). If 9 VAC 5 Chapter 60, Part II, Article 4 (formerly 9 VAC 5 Chapter 40, Part II, Article 3) or 9 VAC 5 Chapter 60, Part II, Article 5 (formerly 9 VAC 5 Chapter 50, Part II, Article 3) of the Virginia Air Regulations are significantly modified or rescinded, the project stakeholders shall consider an alternative system upon which to base this periodic evaluation. Unless the project signatories agree to

change or eliminate this system, the requirements of this subsection shall remain in effect.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 6 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

B. Duration of the PSD Permit

The PSD permit shall continue to be in effect unless terminated as specified in Condition VII.C or Condition VII.F.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 7 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

C. Termination of the PSD Permit

1. The PSD permit may be terminated as provided in Conditions VII.C.2 – VII.C.4 upon written notice for the following reasons only:
 - a. If the EPA or VADEQ determines that continuation of the PSD permit is an imminent and substantial endangerment to public health or welfare, or the environment.
 - b. If the permittee knowingly falsifies emissions data.
 - c. If the permittee receives four consent orders or two judgments adverse to the permittee arising from non-compliance with the PSD permit in a five year period that are deemed material.
 - d. If the total emissions cap is exceeded.
 - e. Upon full consent of all project signatories.
 - f. For other reasons not specified in Condition VII.C.1 for which VADEQ has statutory authority to terminate the PSD permit.
2. Force Majeure Exemption from Condition VII.C.1
 - a. A force majeure is defined as any event arising from causes not reasonably foreseeable and beyond the control of the permittee, which cannot be overcome by due diligence and which delays or prevents performance by a date or manner required by the PSD permit.
 - b. Such force majeure events shall not cause termination of the PSD permit providing that the permittee complies with the notification requirements in Condition VII.C.2.c.

- c. Within seven calendar days after it becomes aware of an event which the permittee claims constitutes a force majeure exemption from Condition VII.C.1, the permittee shall notify EPA and VADEQ. This notification shall include the estimated time anticipated for the delay, its cause, measures taken or to be taken to prevent or minimize the delay, and the estimated timetable for the implementation of these measures.
3. In the event of termination as specified in Condition VII.C.1, the VADEQ or EPA shall provide the project signatories with written notice of its intent to terminate the PSD permit. Within 30 calendar days of the permittee's receipt of this notice, the permittee may take corrective action to remedy the cause of the termination. If this remedy (which may include a corrective action plan and schedule) is deemed acceptable by the regulatory agency that provided written notice of its intent to terminate the permit, the action to terminate the PSD permit shall be withdrawn. Otherwise, the PSD permit is terminated as provided in Condition VII.C.4.
4. If the notice of intent to terminate is not withdrawn by the enforcing agency as provided in Condition VII.C.3, the agreement shall be terminated in the following manner:
 - a. The permittee shall submit a revised Title V application under the then-applicable Title V program no later than 12 months after the notice of intent to terminate, or within some other reasonable shorter time period as agreed to by the Title V-implementing agency and the permittee (called the interim period).
 - b. During this interim period the permittee shall meet with the Title V-implementing agency to agree upon the appropriate applicable requirements to be included in the Title V application and draft permit.
 - c. During this interim period the permittee shall abide by all terms of the PSD permit that are in effect at that time. If the site's actual 12-month rolling total of criteria pollutant emissions equals or exceeds the total emissions cap, increases of these emissions shall be allowed only with prior approval from the permitting authority(ies) and receipt of any necessary preconstruction permits.
 - d. Once the revised Title V permit application is submitted and deemed complete, the Title V-implementing agency shall issue an order stipulating that the site shall operate under the requirements as specified in the Title V application and in compliance with all applicable requirements. Upon issuance of the order the PSD permit would be terminated.

5. Termination of the PSD permit does not cancel the permittee's obligation to complete any corrective actions relating to non-compliance under the PSD permit.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 8 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

D. Inspection and Entry

1. Upon presentation of credentials and other documents as may be required by law, the permittee shall allow authorized representatives of EPA and VADEQ to perform the following:
 - a. Enter upon the site.
 - b. Have access to and copy at reasonable times any records that must be kept under the conditions of the PSD permit.
 - c. Have access at reasonable times to batch and other plant records needed to verify emissions.
 - d. Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations required under the PSD permit.
 - e. Sample or monitor any substances or parameters at any location, during operating hours, for the purpose of assuring PSD permit compliance or as otherwise authorized by the Clean Air Act.
2. No person shall obstruct, hamper, or interfere with any such authorized representative while in the process of carrying out his official duties. Refusal of entry or access may constitute grounds for PSD permit violation and assessment of civil penalties.
3. Such site, facility and equipment access, and sampling and monitoring shall be subject to the permittee's safety and industrial hygiene procedures, and Food and Drug Administration and Good Manufacturing Practice requirements in force at the site.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 9 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

E. Reservation of Rights

1. Except as expressly provided in the PSD permit:
 - a. Each project signatory reserves all rights and defenses it may have, and
 - b. Nothing herein shall prevent EPA or VADEQ from taking administrative enforcement measures or seeking legal or equitable relief to enforce the terms of the PSD permit, including but not limited to the right to seek injunctive relief, and imposition of statutory penalties, fines and/or punitive damages.
2. Nothing herein shall be construed to limit the rights of EPA or VADEQ to undertake any criminal enforcement activity against the permittee or any person.
3. Nothing herein shall be construed to limit the authority of EPA or VADEQ to undertake any actions in response to conditions which present an imminent and substantial endangerment to public health or welfare, or the environment.
4. Nothing herein shall be construed to limit the permittee's rights to administrative and judicial appeal of termination actions in accordance with 9 VAC 5 Chapter 170, Part VIII of the State Air Pollution Control Board Regulations for the Control and Abatement of Air Pollution.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 10 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

F. Transfer of Ownership

1. The terms of the PSD permit are transferable to a new owner upon sale of the site.
2. In the event of any change in ownership or control of the site, the permittee shall notify the project stakeholders in writing no later than 10 days after the change. The notification shall include the name, address, telephone number of the transferee in interest, and the date of the transfer.
3. For the first 12 months after change in ownership or control of the site, the new owner shall submit the monthly 12-month rolling total of criteria pollutant emissions to the project signatories, in the same manner as specified in Condition III.B.2.
4. Within 12 months of the change in ownership or control of the site, the PSD permit shall be reviewed as specified in Condition VII.A. Such review shall also include an affirmative renewal of the PSD permit by the project signatories. Affirmative renewal means that the PSD permit shall continue to be in effect if all

project signatories (excluding the former permittee and including the new owner/operator) agree that the PSD permit should continue; otherwise, the PSD permit shall be terminated as specified in Condition VII.C.4.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 11 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

G. Definitions for Terms in the PSD Permit

1. 12-Month Rolling Total: The 12-month rolling total for an individual pollutant or the total of Condition III.A.1.a pollutants is calculated on a monthly basis as the sum of all actual emissions of the respective pollutant(s) from the previous 12 months.
2. Completion of Powerhouse Conversion: The date upon which the new boilers are operational. This determination shall be made by the permittee based on the boiler manufacturer's installation, startup, and shakedown specifications.
3. Compliance Date: The date upon which the site is required to take action in order to comply with a new regulation or a regulation to which it is newly subject.
4. Criteria Pollutant Regulation: A regulation promulgated under the Clean Air Act Title I or Virginia Air Pollution Control Law covering only those pollutants listed in Condition III.A.1.a of this permit.
5. HAP Regulation: A state or federal regulation promulgated under the Clean Air Act Title III.
6. Highest Emission Point (HEP): The highest 12-month rolling total of criteria pollutant emissions from the site since July 12, 2001.
7. Process Unit:
 - a. Manufacturing equipment assembled to produce a single intermediate or final product, or
 - b. Any combustion device.
8. Project Stakeholders: Employees of the project signatories to the Final Project Agreement, plus other parties as follows:
 - a. Up to three other community representatives shall be included as nominated by the Rockingham County Board of Supervisors, and agreed to by full consent of the project signatories to the Final Project Agreement. Community

representatives are defined as local government and/or community residents with an ongoing stake in the project, and

- b. Up to one representative from a regional public interest group shall be included as nominated by any project signatory and agreed to by full consent of the project signatories.
9. PSD Permit: The PSD permit issued on January 7, 1998, with an effective date of February 10, 1998, administratively modified August 8, 2001, and modified 9/18/2006.
10. Responsible Official:
 - a. The president, secretary, treasurer, or vice-president of the business entity in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the business entity; or,
 - b. A duly authorized representative of such business entity if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:
 - (1) The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding \$25 million (in second quarter 1980 dollars), or
 - (2) The authority to sign documents has been assigned or delegated to such representative in accordance with procedures of the business entity.
11. Signatories to the Final Project Agreement or project signatories: The U.S. Environmental Protection Agency (EPA), the Virginia Department of Environmental Quality (VADEQ), the Department of the Interior Federal Land Manager (FLM), the Rockingham County Board of Supervisors, and Merck & Co., Inc. All correspondence required by the PSD permit shall be directed to the individual representatives for each of these project signatories listed in Table VIII. This table may be revised upon written notification to the project signatories.

Table VIII. Individual Signatory Representatives.

Title	Affiliation	Address	Telephone
Director, Air Radiation and Toxics Division	EPA Region III	(3AT00) 1650 Arch Street Philadelphia, PA 19107	215-566-2050
Regional Director	Valley Regional Office VA Department of Environmental Quality	4411 Early Road P.O. Box 3000 Harrisonburg, VA 22801	540-574-7800
Chief, Air Resources Division	National Park Service	P. O. Box 25287 Denver, CO 80225	303-969-2074
Chairman	Rockingham County Board of Supervisors	P. O. Box 1252 Harrisonburg, VA 22801	540-433-5626
Director, Safety and Environment	Safety and Environment Merck & Co., Inc.	2778 South East Side Hwy Elkton, VA 22827-0007	540-298-4046

12. Site: The contiguous property at Route 340 South, Elkton, Virginia, under common control by Merck & Co., Inc., and its successors in ownership, known as the Stonewall site.

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 12 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

VIII. Compliance Plan

A. Description of Compliance Requirements

The permittee is subject to the compliance schedule described below. The schedule includes a schedule of remedial measures, including an enforceable sequence of actions with milestones, leading to compliance with applicable requirements for which the source will be in noncompliance at the time of permit issuance. This compliance schedule resembles and is at least as stringent as that contained in any judicial consent decree or Board order to which the source is subject. This schedule is supplemental to, and does not sanction noncompliance with the applicable requirements upon which it is based. (9 VAC 5-80-90 I.3.c)

B. Compliance Schedule

1. The permittee shall comply with the DEQ-approved plan to operate and maintain the process changes that have been installed and implemented to ensure that control efficiencies for methyl chloride in the Carbidopa process are maintained at the Stonewall facility as demonstrated in performance testing conducted in November 2003. The plan, described in Merck's September 12, 2005 submittal ("Re: Appendix A Item 1 of State Air Pollution Control Board Enforcement Action Order Issued by Consent to Merck & Co., Inc."), includes the following operating and monitoring requirements for the Carbidopa process:

Control device/practice	Operational parameter	Operational parameter value	Monitoring requirement
Nitrogen sweep as described	Nitrogen sweep	Maintain automatic valve in open position	Check once per batch
QU-602B	Water temperature	If < 85 °C	Check every 15 minutes
	Water flow rate	Maximum flow: 1.8 gpm	
	Water temperature	If > or equal to 85 °C	Check every 15 minutes
	Water flow rate	No flow limit	
SCR-634	Packed bed recycle flow	Minimum flow: 23.7 gpm	Check every 15 minutes
	pH	Minimum pH: 2.0	Check once per day
QU-602C	Water temperature	If < 60 °C	Check every 15 minutes
	Water flow rate	Maximum flow: 0.5 gpm	
	Water temperature	If > or equal to 60 °C	Check every 15 minutes
	Water flow rate	No flow limit	
RE-3501	Combustion temperature	Minimum: 1645 °F	Check every 15 minutes
SCR-3500	Packed bed recycle flow	Minimum: 62.8 gpm	Check every 15 minutes
	pH	Minimum: 7.4 pH	Check once per day

(9 VAC 5-80-110)

2. The permittee shall upgrade the portions of the Stonewall facility's chemical sewer system serving pharmaceutical manufacturing operations from which wastewater streams containing organic HAPs (excluding ethylene glycol) are discharged. This upgrade shall bring these portions of the chemical sewer system into conformance with the applicable emission suppression requirements specified in 40 CFR 63.1256. The chemical sewer system upgrade shall include applicable individual drain systems, open sumps, and basins from the point of discharge up to and including the point where the discharge enters the wastewater treatment plant (WWTP). All upgrades to the chemical sewer system shall be completed and in operation no later than July 15, 2007.

(9 VAC 5-80-110)

3. The permittee shall install a fixed roof on TA-115 in the WWTP no later than July 15, 2007.

(9 VAC 5-80-110)

4. The permittee shall complete an engineering assessment to determine the impact of the additional loading of organic HAPs (excluding ethylene glycol) from the projects specified in Conditions VIII.B.2 and VIII.B.3 to the biological treatment unit of the Stonewall facility's WWTP. The permittee shall provide DEQ with the results of this evaluation and a determination concerning the need to conduct additional testing in accordance with 40 CFR Part 63, Appendix C within 180 days of the completion of the two projects.

(9 VAC 5-80-110)

5. The permittee shall sample and analyze at the Stonewall facility's WWTP influent for all organic HAPs (excluding ethylene glycol) for which removal credit in wastewater treatment will be taken, as follows:

- a. Samples shall be collected and analyzed in accordance with DEQ-approved procedures.
- b. Individual organic HAPs (excluding ethylene glycol) from pharmaceutical manufacturing operations shall be sampled and analyzed at the WWTP influent on a daily basis unless the given organic HAP-containing manufacturing operation did not discharge to the WWTP since the previous sample was collected.
- c. The permittee shall maintain records to document when sampling and analysis for specific organic HAPs are required at the WWTP influent in accordance with Condition VIII.B.5b above.
- d. Any organic HAP (excluding ethylene glycol) used in pharmaceutical manufacturing operations and discharged to the WWTP shall be assumed

emitted to the atmosphere if not included in the sampling and analysis procedures.

- e. For instances where one or more daily influent concentration values are determined to be less than the specified limit of quantitation (LOQ), these values shall be treated as zeros in determining monthly average HAP concentrations at the WWTP influent. The monthly average HAP concentrations at the WWTP influent shall be calculated using all available data for the month including the defined zeros.
- f. The permittee shall calculate emissions of organic HAPs (excluding ethylene glycol) from wastewater conveyance systems using the best available information and methods until the fulfillment of Condition VIII.B.2.

(9 VAC 5-80-110)

C. Reporting Requirements

- 1. The permittee shall submit to DEQ a report of the following:
 - a. Rolling 12-month total HAP emissions (individual and in the aggregate) for each month.
 - b. Daily WWTP influent sampling and analysis composite results for each organic HAP (excluding ethylene glycol) or an indication that sampling and analysis was not conducted for the HAP, for each month.

The permittee shall submit these reports within 60 days after the end of each calendar month. These monthly reports shall be submitted until the July 8, 2005 Consent Order is terminated and shall satisfy the quarterly reporting required by Conditions IV.E.1 and IV.E.2 of the Title V permit.

(9 VAC 5-80-110)

- 2. The permittee shall submit to DEQ quarterly reports documenting progress in achieving compliance with Conditions VIII.B.1 through VIII.B.5.

(9 VAC 5-80-110)

D. Certified Progress Report

The permittee shall submit a certified progress report semi-annually detailing the progress made toward completion of the milestones in Compliance Schedule above. The progress report must be certified by a responsible official and shall contain the following:

1. Dates for achieving the activities, milestones, or compliance required in the schedule of compliance, and dates when such activities, milestones, or compliance were achieved.
2. An explanation of why any dates in the schedule of compliance were not or will not be met, and any preventative or corrective measures adopted.

(9 VAC 5-80-90 I.4 and 9 VAC 5-80-110 K.4)

IX. Insignificant Emission Units

The following emission units at the facility are identified in the application as insignificant emission units under 9 VAC 5-80-720:

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
See Attachment C			

These emission units are presumed to be in compliance with all requirements of the federal Clean Air Act as may apply. Based on this presumption, no monitoring, recordkeeping, or reporting shall be required for these emission units in accordance with 9 VAC 5-80-110.

X. Compliance With State and Federal Regulations and Air Permits Under PSD (Project XL) Permit

The PSD permit allows the permittee to construct or modify emission units at the site. Any such permitted activities would not be subject to any further PSD, NSR, or minor NSR preconstruction requirements for the pollutants as specified in Conditions X.B and X.C.

A. Powerhouse Conversion: Regulatory Compliance for the Powerhouse

Compliance with the PSD permit shall be deemed to be compliance with all requirements of 40 CFR 60 Subpart Db (40 CFR 60.40b et seq.) and 9 VAC 5 Chapter 50, Part II, Article 5 (9 VAC 5-50-400 et seq.). (9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, 40 CFR 60.49b(u) and Section 2 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

B. Major New Source Review (NSR) Permitting and Registration

Compliance with the PSD permit shall be deemed to satisfy all requirements of the major NSR permitting and registration regulations (40 CFR 52.21, 40 CFR 52.2420 as it pertains to major NSR permitting and registration, and VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 4 (9 VAC 5-50-240 et seq.), 9 VAC 5 Chapter 80, Part II, Article 8 (9 VAC 5-80-1700 et seq.), 9 VAC 5-80-30, and 9 VAC 5-20-160) for pollutants listed in Condition III.A.1.a and particulate matter (PM), but not for particulate matter regulated as PM-2.5.

C. Other Regulations for which the PSD permit constitutes Compliance

Compliance with the PSD permit shall be deemed to satisfy all requirements of the following regulations for all pollutants except lead, except particulate matter regulated as PM-2.5, and except any new criteria pollutants listed by EPA in 40 CFR 52.21(b)(23)(i) after January 7, 1998:

1. Minor NSR Permitting and Registration

40 CFR 52.2420 as it pertains to minor NSR permitting and registration, and VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 4 (9 VAC 5-50-240 et seq.), 9 VAC 5 Chapter 80, Part II, Article 6 (formerly 9 VAC 5-80-10 and 9 VAC 5-80-11), and 9 VAC 5-20-160

2. Standards of Performance for Stationary Sources

VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 4 (9 VAC 5-50-240 et seq.), and 40 CFR 52.2420, as it pertains to 9 VAC 5-50-240 et seq., standards of performance for stationary sources

3. Virginia Air Toxics Rule

VA Air Regulations 9 VAC 5 Chapter 60, Articles 4 and 5 (9 VAC 5-60-200 et seq. and 9 VAC 5-60-300 et seq.) (formerly 9 VAC 5 Chapter 40, Part II, Article

3 (9 VAC 5-40-160 et seq.) and 9 VAC 5 Chapter 50, Part II, Article 3 (9 VAC 5-50-160 et seq.))

4. Notification, Records, and Reporting

VA Air Regulations 9 VAC 5-40-50 and 9 VAC 5-50-50, and 40 CFR 52.2420 as it pertains to 9 VAC 5-40-50 and 9 VAC 5-50-50, notification, records, and reporting

5. Emission Standards for General Process Operations, Incinerators, and Fuel Burning Equipment

VA Air Regulations 9 VAC 5 Chapter 40, Part II, Article 4 (9 VAC 5-40-240 et seq.); 9 VAC 5 Chapter 40, Part II, Article 7 (9 VAC 5-40-730 et seq.); and, 9 VAC 5 Chapter 40, Part II, Article 8 (9 VAC 5-40-880 et seq.), and 40 CFR 52.2420, as it pertains to VA Air Regulations 9 VAC 5 Chapter 40, Part II, Article 4; 9 VAC 5 Chapter 40, Part II, Article 7; and, 9 VAC 5 Chapter 40, Part II, Article 8, Emission Standards for General Process Operations, Incinerators, and Fuel Burning Equipment

6. Compliance and Monitoring

VA Air Regulations 9 VAC 5-40-20, 9 VAC 5-40-21, 9 VAC 5-40-22, 9 VAC 5-40-40, 9 VAC 5-40-41 and 9 VAC 5-50-40, and 40 CFR 52.2420, as it pertains to 9 VAC 5-40-20, 9 VAC 5-40-21, 9 VAC 5-40-22, 9 VAC 5-40-40, 9 VAC 5-40-41 and 9 VAC 5-50-40, compliance and monitoring

7. RCRA Organic Air Emissions Standards

40 CFR 264 Subparts AA and BB (40 CFR 264.1030 et seq. and 264.1050 et seq.), and 40 CFR 265 Subparts AA and BB (40 CFR 265.1030 et seq. and 265.1050 et seq.)

D. Regulations for which the PSD permit Constitutes Compliance for Certain Provisions

Compliance with the PSD permit shall be deemed to satisfy certain requirements of the following regulations for all pollutants, except lead, except particulate matter regulated as PM-2.5, and except for any new criteria pollutants listed by EPA in 40 CFR 52.21(b)(23)(i) after January 7, 1998. The permittee shall continue to comply with other sections of these rules as specified in the regulations. These regulations and the portions for which the PSD permit constitutes compliance are specified below.

1. Standards of Performance for New Stationary Sources (NSPS)

The PSD permit constitutes compliance with 40 CFR 60 Subpart Kb (40 CFR 60.110b et seq.), 40 CFR 60 Subpart A (40 CFR 60.1 et seq.), VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 5 (9 VAC 5-50-400 et seq.), and 40 CFR 52.2420 as it pertains to VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 5, for new and existing bulk volatile organic liquid storage vessels

(including petroleum liquid storage vessels) that would otherwise only be subject to notification, recordkeeping, and reporting requirements.

2. Title V Permitting

- a. Monitoring requirements: Monitoring requirements specified in Condition III.B.2 of this permit shall constitute compliance with any applicable monitoring requirements in 40 CFR 71.6(a)(3) and 9 VAC 5-80-110 E that would be applicable to the provisions of the PSD permit.
- b. Recordkeeping and Reporting Requirements: Recordkeeping and reporting requirements specified in Condition III.B.2 of this permit shall constitute compliance with recordkeeping and reporting requirements that would be applicable to provisions of the PSD permit in 40 CFR 71.6(a)(3)(ii), 40 CFR 71.6(a)(3)(iii)(A), 9 VAC 5-80-110.F.1, and 9 VAC 5-80-110.F.2.a

3. CERCLA and EPCRA Emergency Release Reporting (40 CFR 302 and 40 CFR 355.40)

Emissions in compliance with the PSD permit are “federally permitted releases” for purposes of release reporting under Section 103(a) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and Section 304 of the Emergency Planning and Community Right-to-Know Act (EPCRA)

4. Facility and control equipment maintenance or malfunction compliance

VA Air Regulations 9 VAC 5-20-180 and 9 VAC 5-50-20, and 40 CFR 52.2420 as it pertains to 9 VAC 5-20-180 and 9 VAC 5-50-20, Facility and Control Equipment Maintenance or Malfunction Compliance (except for visible emissions and odor)

5. Control Programs

VA Air Regulations 9 VAC 5-20-170, and 40 CFR 52.2420 as it pertains to 9 VAC 5-20-170, Control Programs (except for visible emissions and odor)

6. Compliance, Monitoring, and Performance Testing

VA Air Regulations 9 VAC 5-40-30, 9 VAC 5-50-30, and 40 CFR 52.2420 as it pertains to 9 VAC 5-40-30 and 9 VAC 5-50-30, Compliance, Monitoring and, Performance Testing (all except 9 VAC 5-40-30B and 9 VAC 5-50-30B, which subject emission testing to approved guidelines)

7. RCRA Organic Air Emissions Standards for Tanks and Containers

40 CFR 264 Subpart CC (40 CFR 264.1080 et seq.), and 40 CFR 265 Subpart CC (40 CFR 265.1080 et seq.), except for provisions applicable to surface impoundments

- E. Compliance with the terms of the PSD permit shall not relieve the permittee of its obligation to comply with applicable local, State, or Federal laws and regulations not addressed in Section IX of this permit.**
- F. Violation of a term of the PSD permit shall not constitute a violation of regulations listed in Section IX of this permit for which the permit constitutes compliance.**

(9 VAC 5-80-110, 9 VAC 5 Chapter 190, 40 CFR 52.2454, and Section 3 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified 9/18/2006)

XI. Permit Shield & Inapplicable Requirements

Compliance with the provisions of this permit shall be deemed compliance with all applicable requirements in effect as of the permit issuance date as identified in this permit. This permit shield covers only those applicable requirements covered by terms and conditions in this permit and the following requirements which have been specifically identified as being not applicable to this permitted facility:

Citation	Title of Citation	Description of Applicability
40 CFR 60 Subpart III (9 VAC 5-50-410, Subpart III)	Volatile Organic Compound (VOC) Emissions from the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes	Applicable to air oxidation unit processes manufacturing regulated (listed) chemicals; Stonewall Plant does not operate an air oxidation unit process
40 CFR 60 Subpart RRR (9 VAC 5-50-410, Subpart RRR)	VOC Emissions from SOCMI Reactor Processes	Applicable to specified reactor processes manufacturing regulated (listed) chemicals; Stonewall Plant does not operate the affected reactor processes (rule exempts any reactor process designed and operated as a batch operation)
40 CFR 60 Subpart VV (9 VAC 5-50-410, Subpart VV)	Equipment Leaks of VOC in the SOCMI	Applicable to SOCMI facilities that produce one or more chemicals listed in 40 CFR 60.489; Stonewall Plant does not produce listed chemicals
40 CFR 60 Subpart NNN (9 VAC 5-50-410, Subpart NNN)	VOC Emissions from SOCMI Distillation Operations	Applicable to SOCMI facilities that produce one or more chemicals listed in 40 CFR 60.489; Stonewall Plant does not produce listed chemicals
40 CFR 60 Subpart YYY (9 VAC 5-50-410, Subpart YYY)	VOC Emissions from SOCMI Wastewater Operations	Applicable to SOCMI facilities that produce one or more chemicals listed in 40 CFR 60.489; Stonewall Plant does not produce listed chemicals

Nothing in this permit shield shall alter the provisions of §303 of the federal Clean Air Act, including the authority of the administrator under that section, the liability of the owner for any violation of applicable requirements prior to or at the time of permit issuance, or the ability to obtain information by (i) the administrator pursuant to §114 of the federal Clean Air Act, (ii) the Board pursuant to §10.1-1314 or §10.1-1315 of the Virginia Air Pollution Control Law or (iii) the Department pursuant to §10.1-1307.3 of the Virginia Air Pollution Control Law.
 (9 VAC 5-80-140)

XII. General Conditions

A. Federal Enforceability

All terms and conditions in this permit are enforceable by the administrator and citizens under the federal Clean Air Act, except those that have been designated as only state-enforceable.

(9 VAC 5-80-110 N)

B. Permit Expiration

This permit has a fixed term of five years. The expiration date shall be the date five years from the date of issuance. Unless a timely and complete renewal application consistent with 9 VAC 5-80-80 has been submitted, to the Department, by the owner, the right of the facility to operate shall be terminated upon permit expiration.

1. The owner shall submit an application for renewal at least six months but no earlier than eighteen months prior to the date of permit expiration.
2. If an applicant submits a timely and complete application for an initial permit or renewal under this section, the failure of the source to have a permit or the operation of the source without a permit shall not be a violation of Article 1, Part II of 9 VAC 5 Chapter 80, until the Board takes final action on the application under 9 VAC 5-80-150.
3. No source shall operate after the time that it is required to submit a timely and complete application under subsections C and D of 9 VAC 5-80-80 for a renewal permit, except in compliance with a permit issued under Article 1, Part II of 9 VAC 5 Chapter 80.
4. If an applicant submits a timely and complete application under section 9 VAC 5-80-80 for a permit renewal but the Board fails to issue or deny the renewal permit before the end of the term of the previous permit, (i) the previous permit shall not expire until the renewal permit has been issued or denied and (ii) all the terms and conditions of the previous permit, including any permit shield granted pursuant to 9 VAC 5-80-140, shall remain in effect from the date the application is determined to be complete until the renewal permit is issued or denied.
5. The protection under subsections F 1 and F 5 (ii) of section 9 VAC 5-80-80 F shall cease to apply if, subsequent to the completeness determination made pursuant section 9 VAC 5-80-80 D, the applicant fails to submit by the deadline specified in writing by the Board any additional information identified as being needed to process the application.

(9 VAC 5-80-80 B, C and F, 9 VAC 5-80-110 D and 9 VAC 5-80-170 B)

C. Annual Compliance Certification

Exclusive of any reporting required to assure compliance with the terms and conditions of this permit or as part of a schedule of compliance contained in this permit, the permittee shall submit to EPA and DEQ no later than **March 1** each calendar year a certification of compliance with all terms and conditions of this permit including emission limitation standards or work practices. The compliance certification shall comply with such additional requirements that may be specified pursuant to §114(a)(3) and §504(b) of the federal Clean Air Act. This certification shall be signed by a responsible official, consistent with 9 VAC 5-80-80 G, and shall include:

1. The time period included in the certification. The time period to be addressed is January 1 to December 31.
2. The identification of each term or condition of the permit that is the basis of the certification.
3. The compliance status.
4. Whether compliance was continuous or intermittent, and if not continuous, documentation of each incident of non-compliance.
5. Consistent with Condition III.B.2 and Sections IV.B, C, and D, VI.B, C, and D, and, as applicable, V.B, C, and E of this permit, the method or methods used for determining the compliance status of the source at the time of certification and over the reporting period.
6. Such other facts as the permit may require to determine the compliance status of the source.
7. One copy of the annual compliance certification shall be sent to EPA at the following address:

Clean Air Act Title V Compliance Certification (3AP00)
U. S. Environmental Protection Agency, Region III
1650 Arch Street
Philadelphia, PA 19103-2029.

(9 VAC 5-80-110 K.5)

D. Permit Deviation Reporting

The permittee shall notify the Director, Valley Region, within four daytime business hours after discovery of any deviations from permit requirements which may cause excess emissions for more than one hour, including those attributable to upset

conditions as may be defined in this permit. In addition, within 14 days of the discovery, the permittee shall provide a written statement explaining the problem, any corrective actions or preventative measures taken, and the estimated duration of the permit deviation. The occurrence should also be reported in the next annual compliance monitoring report pursuant to General Condition XII.C of this permit. (9 VAC 5-80-110 F.2 and 9 VAC 5-80-250)

E. Failure/Malfunction Reporting

If, for any reason, the affected facilities or related air pollution control equipment fails or malfunctions and may cause excess visible emissions for more than one hour, the owner shall notify the Director, Valley Region, within four (4) daytime business hours of discovery of the occurrence. In addition, the owner shall provide a written statement, within 14 days of discovery of the occurrence, explaining the problem, corrective action taken, and the estimated duration of the breakdown/shutdown.(9 VAC 5-20-180 C and Section 3.4.4 of 2/10/1998 Permit, administratively modified 8/8/2001 and modified x9/18/2006)

F. Severability

The terms of this permit are severable. If any condition, requirement or portion of the permit is held invalid or inapplicable under any circumstance, such invalidity or inapplicability shall not affect or impair the remaining conditions, requirements, or portions of the permit. (9 VAC 5-80-110 G.1)

G. Duty to Comply

The permittee shall comply with all terms and conditions of this permit. Any permit noncompliance constitutes a violation of the federal Clean Air Act or the Virginia Air Pollution Control Law or both and is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or, for denial of a permit renewal application. (9 VAC 5-80-110 G.2)

H. Need to Halt or Reduce Activity not a Defense

It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit. (9 VAC 5-80-110 G.3)

I. Permit Action for Cause

This permit may be modified, revoked, reopened, and reissued, or terminated for cause as specified in 9 VAC 5-80-110 L, 9 VAC 5-80-240 and 9 VAC 5-80-260. The filing of a request by the permittee for a permit modification, revocation and

reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit condition.
(9 VAC 5-80-110 G.4)

J. Property Rights

The permit does not convey any property rights of any sort, or any exclusive privilege.
(9 VAC 5-80-110 G.5)

K. Duty to Submit Information

1. The permittee shall furnish to the Board, within a reasonable time, any information that the Board may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the permittee shall also furnish to the Board copies of records required to be kept by the permit and, for information claimed to be confidential, the permittee shall furnish such records to the Board along with a claim of confidentiality.
(9 VAC 5-80-110 G.6)
2. Any document (including reports) required in a permit condition to be submitted to the Board shall contain a certification by a responsible official that meets the requirements of 9 VAC 5-80-80 G.
(9 VAC 5-80-110 K.1)

L. Duty to Pay Permit Fees

The owner of any source for which a permit under 9 VAC 5-80-50 through 9 VAC 5-80-300 was issued shall pay permit fees consistent with the requirements of 9 VAC 5-80-310 through 9 VAC 5-80-350. The actual emissions covered by the permit program fees for the preceding year shall be calculated by the owner and submitted to the Department by **April 15** of each year. The calculations and final amount of emissions are subject to verification and final determination by the Department.
(9 VAC 5-80-110 H and 9 VAC 5-80-340 C)

M. Fugitive Dust Emission Standards

During the operation of a stationary source or any other building, structure, facility, or installation, no owner or other person shall cause or permit any materials or property to be handled, transported, stored, used, constructed, altered, repaired, or demolished without taking reasonable precautions to prevent particulate matter from becoming airborne. Such reasonable precautions may include, but are not limited to, the following:

1. Use, where possible, of water or chemicals for control of dust in the demolition of existing buildings or structures, construction operations, the grading of roads, or the clearing of land;
2. Application of asphalt, water, or suitable chemicals on dirt roads, materials stockpiles, and other surfaces which may create airborne dust; the paving of roadways and the maintaining of them in a clean condition;
3. Installation and use of hoods, fans, and fabric filters to enclose and vent the handling of dusty material. Adequate containment methods shall be employed during sandblasting or other similar operations;
4. Open equipment for conveying or transporting material likely to create objectionable air pollution when airborne shall be covered or treated in an equally effective manner at all times when in motion; and,
5. The prompt removal of spilled or tracked dirt or other materials from paved streets and of dried sediments resulting from soil erosion.

(9 VAC 5-40-90 and 9 VAC 5-50-90)

N. Alternative Operating Scenarios

Contemporaneously with making a change between reasonably anticipated operating scenarios identified in this permit, the permittee shall record in a log at the permitted facility a record of the scenario under which it is operating. The permit shield described in 9 VAC 5-80-140 shall extend to all terms and conditions under each such operating scenario. The terms and conditions of each such alternative scenario shall meet all applicable requirements including the requirements of 9 VAC 5 Chapter 80, Article 1.

(9 VAC 5-80-110 J)

O. Reopening For Cause

The permit shall be reopened by the Board if additional federal requirements become applicable to a major source with a remaining permit term of three years or more. Such reopening shall be completed no later than 18 months after promulgation of the applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which the permit is due to expire, unless the original permit or any of its terms and conditions has been extended pursuant to 9 VAC 5-80-80 F.

1. The permit shall be reopened if the Board or the administrator determines that the permit contains a material mistake or that inaccurate statements were made in establishing the emissions standards or other terms or conditions of the permit.

2. The permit shall be reopened if the administrator or the Board determines that the permit must be revised or revoked to assure compliance with the applicable requirements.
3. The permit shall not be reopened by the Board if additional applicable state requirements become applicable to a major source prior to the expiration date established under 9 VAC 5-80-110 D.

(9 VAC 5-80-110 L)

P. Permit Availability

Within five days after receipt of the issued permit, the permittee shall maintain the permit on the premises for which the permit has been issued and shall make the permit immediately available to DEQ upon request.

(9 VAC 5-80-150 E)

Q. Transfer of Permits

1. No person shall transfer a permit from one location to another, unless authorized under 9 VAC 5-80-130, or from one piece of equipment to another.
(9 VAC 5-80-160)
2. In the case of a transfer of ownership of a stationary source, the new owner shall comply with any current permit issued to the previous owner. The new owner shall notify the Board of the change in ownership within 30 days of the transfer and shall comply with the requirements of 9 VAC 5-80-200.
(9 VAC 5-80-160)
3. In the case of a name change of a stationary source, the owner shall comply with any current permit issued under the previous source name. The owner shall notify the Board of the change in source name within 30 days of the name change and shall comply with the requirements of 9 VAC 5-80-200.
(9 VAC 5-80-160)

R. Malfunction as an Affirmative Defense

1. A malfunction constitutes an affirmative defense to an action brought for noncompliance with technology-based emission limitations if the conditions of paragraph 2 are met.
2. The affirmative defense of malfunction shall be demonstrated by the permittee through properly signed, contemporaneous operating logs, or other relevant evidence that show the following:

- a. A malfunction occurred and the permittee can identify the cause or causes of the malfunction.
- b. The permitted facility was at the time being properly operated.
- c. During the period of the malfunction the permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in the permit.
- d. The permittee notified the Board of the malfunction within two working days following the time when the emissions limitations were exceeded due to the malfunction. This notification shall include a description of the malfunction, any steps taken to mitigate emissions, and corrective actions taken. The notification may be delivered either orally or in writing. The notification may be delivered by electronic mail, facsimile transmission, telephone, telegraph, or any other method that allows the permittee to comply with the deadline. The notice fulfills the requirement of 9 VAC 5-80-110 F.2. b to report promptly deviations from permit requirements. This notification does not release the permittee from the malfunction reporting requirements under 9 VAC 5-20-180 C as they pertain to visible or HAP emissions.
- e. In any enforcement proceeding, the permittee seeking to establish the occurrence of a malfunction shall have the burden of proof.
- f. The provisions of this section are in addition to any malfunction, emergency or upset provision contained in any applicable requirement.

(9 VAC 5-80-250)

S. Permit Revocation or Termination for Cause

A permit may be revoked or terminated prior to its expiration date if the owner knowingly makes material misstatements in the permit application or any amendments thereto or if the permittee violates, fails, neglects or refuses to comply with the terms or conditions of the permit, any applicable requirements, or the applicable provisions of 9 VAC 5 Chapter 80 Article 1. The Board may suspend, under such conditions and for such period of time as the Board may prescribe, any permit for any of the grounds for revocation or termination or for any other violations of these regulations.

(9 VAC 5-80-190 C and 5-80-260)

T. Duty to Supplement or Correct Application

Any applicant who fails to submit any relevant facts or who has submitted incorrect information in a permit application shall, upon becoming aware of such failure or incorrect submittal, promptly submit such supplementary facts or corrections. An

applicant shall also provide additional information as necessary to address any requirements that become applicable to the source after the date a complete application was filed but prior to release of a draft permit.
(9 VAC 5-80-80 E)

U. Stratospheric Ozone Protection

If the permittee handles or emits one or more Class I or II substances subject to a standard promulgated under or established by Title VI (Stratospheric Ozone Protection) of the federal Clean Air Act, the permittee shall comply with all applicable sections of 40 CFR Part 82, Subparts A to F.
(40 CFR Part 82, Subparts A-F)

V. Asbestos Requirements

The permittee shall comply with the requirements of National Emissions Standards for Hazardous Air Pollutants (40 CFR 61) Subpart M, National Emission Standards for Asbestos as it applies to the following: Standards for Demolition and Renovation (40 CFR 61.145), Standards for Insulating Materials (40 CFR 61.148), and Standards for Waste Disposal (40 CFR 61.150).
(9 VAC 5-60-70 and 9 VAC 5-80-110 A.1)

W. Accidental Release Prevention

If the permittee has more, or will have more than a threshold quantity of a regulated substance in a process, as determined by 40 CFR 68.115, the permittee shall comply with the requirements of 40 CFR Part 68.
(40 CFR Part 68)

Attachment A:
Emission Units Having Uncontrolled PM/PM-10 Emission Rates
of Less than Five Tons per Year

<u>Factory 1</u>	<u>Factory 2</u>	<u>Factory 5</u>	<u>Factory 6</u>	<u>Factory 8</u>
CE-511	TA-1108	TA-106	RE-221	FD-9900
RE-506	GB-1108	F-14		VP-9950
RE-508	FD-1206	F-15		WS-9900
RE-601	TOU-2542	F-16		GB-9605
RE-601A	SCR-2546	F-17	<u>Factory 7</u>	ST-9800
TA-73	HP-2604	G-3	TA-800	EF-9075
TA-701	HP-2606	G-4	FD-845	TA-9754 funnel
ST-604	HP-2612	G-5	DC-845	TA-9754
TA-608	HP-2614	G-6	VP-1075	ST-9600
VJ-609	HP-2616	G-7	VP-1075-1	BT-9615
TA-621	HP-2721	G-8	FD-845	ST-9700
TA-606	HP-2721A	G-9	DC-845	FD-9980
TA-710	TA-2604	G-10	VJ-472C	
TA-704	TA-2612	G-11	MI-855	
DR-913	TA-2614	G-12	GB-860	
MI-916	TA-2616	G-13	VP-1040	<u>Building 5</u>
BN-917	BD-1552	G-14	VP-1041	Antibiotic filling line
FD-850	CE-1200	G-15	VP-1050	Antibiotic blending
SCR-601	CE-1400	G-16	VP-1051	MX-121
DC-850	GB-2242	G-27	GB-760	HO-122
CE-821	RE-2242	G-28	GB-765	HB-122
DR-914	TA-2721	G-29	TA-714	MX-185
DI-910	TA-2606	G-30	MI-900	HO-221
Buggy	TA-1277	G-31	TA-725	HO-201
DR-713	TA-1263	G-32	WS-508	IBC for MI-125
	RE-1267	G-34	GB-775	EM-201
	RE-1269	F-1	TA-734	EM-202
	RE-1425	F-2	GB-915	EM-221
	CR-1205	F-3	GB-925	Lakso filler
	CR-1281	F-4		Crixivan house
	GB-2270	F-5		vacuum
	RE-2270	F-10	<u>Utilities</u>	RB-331
	RE-2275	F-11	LTE-125	RB-332
	GB-2263	F-12	LTE-127	IBC (after batch
	RE-2263	G-17	Boiler #7	transfer from
	RE-1277	G-18	and #8 (natural	RC-330 & 333)
	HP-1580	G-24	gas combustion)	TA-210
	PK-1590	G-25		CM-233
	PTS-2270 H	G-26		CM-234
		G-1		CP-238
		G-2		CP-249
		FE-3110		TA-250/255
		FE-3210		
		FE-3310		
		TA-1130		
		TA-1140		

Applicable Requirements from 40 CFR 63 Subpart GGG (National Emission Standards for Hazardous Air Pollutants from Pharmaceuticals Production)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
A. General - Standards					
A.1	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Definitions	Terms used in subpart GGG are defined in the MACT, in Subpart A of Part 63, or in 40 CFR 63.1251. If the same term is defined in subpart A of Part 63 and 40 CFR 3.1251, it shall have the meaning given in 40 CFR 63.1251 for the purposes of subpart GGG	40 CFR 63.1251
A.2	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Each owner or operator of any affected source subject to 40 CFR 63 subpart GGG shall control HAP emissions to the level specified in 40 CFR 63.1252 on and after the site becomes a major source. Initial compliance with the emissions limits shall be demonstrated in accordance with the provisions of 40 CFR 63.1257, and continuous compliance shall be demonstrated in accordance with the provisions of 40 CFR 63.1258.	40 CFR 63.1252
A.3	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Safety Device is allowed to open at any time conditions require it to do so to avoid unsafe conditions.	40 CFR 63.1252(a)
A.4	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	The owner or operator of a closed vent system that contains bypass lines that could divert a vent stream away from a control device used to comply with the requirements in 40 CFR 63.1253, 63.1254, and 63.1256 shall comply with the requirements of Table 4 of 40 CFR 63 subpart	40 CFR 63.1252(b)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				GGG and 40 CFR 63.1252(b)(1) or 63.1252(b)(2). Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this paragraph.	
A.5	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Closed vent systems that contain by-pass lines shall install, maintain and calibrate a flow indicator at the entrance of the by-pass line that will record flow every 15 minutes. Records shall be maintained as specified in 40 CFR 63.1259(i)(6)(i). The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere; or	40 CFR 63.1252(b)(1)
A.6	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	Closed vent systems that contain by-pass lines must secure the by-pass line valve in the closed position with a car seal or lock and key type configuration. Visual inspection of closure mechanism must be conducted at least monthly. Records shall be maintained as specified in 40 CFR 63.1259(i)(6)(ii).	40 CFR 63.1252(b)(2)
A.7	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	Except as provided in 40 CFR 63.1252(c)(2), owners and operators of affected sources shall comply with the requirements of 40 CFR 63.12.1252 c(1) for heat exchange systems that cool process equipment or materials used in pharmaceutical manufacturing operations.	40 CFR 63.1252 c
A.8	General	11, 21, 22, 41, 42, 72, 73, 74,	Emission control/standard	Heat Exchange Systems shall be treated according to 40 CFR 61.104, except for the	40 CFR 63.1252(c)(1)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
		75, 81, F, 23 (Dorzolamide)		monitoring frequency shall be no less than quarterly.	
A.9	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	For identifying leaking equipment, the owner or operator of heat exchange systems on equipment which meet current good manufacturing practices requirements of 21 CFR Part 211 may elect to use physical integrity of the reactor as the surrogate indicator of heat exchange system leaks around the reactor.	40 CFR 63.1252(c)(2)
A.10	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	For storage tanks or process vents subject to 40 CFR 63.1253 and 63.1254 may chose to comply with the emissions averaging option (40 CFR 63.1257 (g) or (h)) subject to the following provisions: (1) State may prohibit averaging of HAPs and mandate source to comply with provisions with 40 CFR 63.153 and 63.154, (2) The averaging group will consist of storage tanks which limit HAP emissions by 90-95% and process vents that reduce emissions by 93% or greater, (3) Average group will not include permanently shutdown processes or storage tank permanently taken out of service, (4) Emissions-averaging may not include processes or storage tanks already controlled on or by November 15, 1990, except when the level of control has increased since that time, (5) Emission points controlled by another regulation may not be credited unless the control has been increased on or after November 15,1990 above any requirement, (6) Emissions-averaging group may	40 CFR 63.1252(d)(1-8)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				not include more than 20 processes and 20 storage tanks, (7) compliance with the emission standards in 40 CFR 63.1253 shall be satisfied when the annual percent reduction is greater than the removal efficiencies specified for storage tanks (90 or 95% as applicable) as demonstrated by procedures in 40 CFR 63.1257(g), (8) Compliance with 40 CFR 63.1253 will be satisfied for storage tanks storing a liquid with a maximum true vapor pressure greater than or equal to 13.1 kPa for capacity between 38m ³ and 75m ³ when the annual emission reduction is 90% or greater and for capacity of greater than or equal to 75m ³ with annual emissions reduction of 95% or greater.	
A.11	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	Pollution prevention alternatives may be used for situations where processes are in series or merged. They will be subject to the following conditions: baseline years will be a single year no earlier than 1992, PMPU shall keep same definition except it may contain multiple processes, nondedicated formulation and solvent recovery are not included.	40 CFR 63.1252(e)(4)(i-iii)
A.12	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	Halogen vents controlled by combustion devices must reduce hydrogen halide emissions by 95% or to less than or equal to 20 ppmv for control devices before the combustion device, or to less than or equal to 20 ppmv for control devices before the combustion device.	40 CFR 63.1252(g)(1-2)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
A.13	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	Planned routine maintenance for centralized combustion control devices. The owner or operator may operate non-dedicated PMPU's during periods of planned routine maintenance for CCCD in accordance with the provisions specified in 40 CFR 63.1252(h)(1) - (6).	40 CFR 63.1252(h)
A.14	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	During maintenance, back-up control devices are necessary.	40 CFR 63.1252(h)(1)
A.15	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	HAP Process vent emissions (greater than 15 lbs./day) must be routed to closed vent system to a condenser meeting the following conditions: (i) Outlet temperature must be less than -50 °C if the partial pressure of the HAP is greater than 20 kPa (2.9 psia), (ii) the outlet temperature must be less than -5 °C if the partial pressure of the HAP is less than 20 kPa (2.9 psia). This partial pressure must be determined at 25 °C.	40 CFR 63.1252(h)(2)(i-iii)
A.16	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	HCl (greater than 15 lbs./day) emissions must be routed to caustic scrubber with a pH of >9.	40 CFR 63.1252(h)(3)
A.17	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	Process vent under 40 CFR 63.1252 is any vent from a unit operation, this does not include those streams that are made up of multiple unit operations that manifold into a single header.	40 CFR 63.1252(h)(4)
A.18	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23	Emission control/standard	Total planned maintenance as specified in 40 CFR 63.1252 shall not exceed 240 hours in any 365-day period.	40 CFR 63.1252(h)(5)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
		(Dorzolamide)			
A.19	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission control/standard	Process vents while being controlled as specified in 40 CFR 63.1252(h)(2) and (3) may not be used in emissions averaging.	40 CFR 63.1252(h)(6)
B. Storage Tanks					
B.1	Storage tanks	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Except as provided in 63.1253(d), (e), and (f), the owner or operator of a storage tank meeting the criteria of (a)(1) of this section is subject to the requirements of 63.1253(b). Except as provided in 63.1253(d), (e), and (f), the owner or operator of a storage tank meeting the criteria of (a)(2) is subject to the requirements of (c). Compliance with the provisions of paragraphs (b) and (c) shall be demonstrated using the initial compliance procedures in 63.1257(c) and the monitoring requirements in 63.1258.	40 CFR 63.1253(a)
B.2	Storage tanks	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Capacity between 38m ³ and 75m ³ (10,038 gal ≤ V < 19813 gal) storing a liquid with a maximum true vapor pressure greater than or equal to 13.1 kPa shall comply with 63.1253(b) -- cover tank with a fixed roof with internal floating roof, external floating roof, an external floating roof converted to an internal, or closed-vent system with control device meeting the conditions of 63.1252(b) with a control device that meets any of the following conditions:	40 CFR 63.1253(a)(1)
B.2.a	Storage tanks	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23	Emission/control standard	Control Device should reduce total inlet HAP Emissions by 90 % weight.	40 CFR 63.1253(b)(1)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
		(Dorzolamide)			
B.2.b	Storage tanks	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Is an enclosed combustion device that provides a minimum residence time of 0.5 seconds at a minimum temperature of 760 °C	40 CFR 63.1253(b)(3)
B.2.c	Storage tanks	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Capacity greater than or equal to 75m ³ (19,813 gal) storing a liquid with a vapor pressure greater than or equal to 13.1 kPa is subject to the requirements of 40 CFR 63.1253 (c)	40 CFR 63.1253(a)(2), 63.1253 (c)
B.3	Storage tanks	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Owner or operator of a storage tank shall equip the affected storage tank with either a fixed roof with internal floating roof, external floating roof, an external floating roof converted to an internal, or closed-vent system meeting the conditions of 40 CFR 63.1252(b) with a control device that meets:	40 CFR 63.1253 (c)
B.3.a	Storage tanks	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Control Device must reduce inlet HAP emissions by greater than or equal to 95 % weight.	40 CFR 63.1253(c)(1)(i)
B.3.b	Storage tanks	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Control Devices installed before April 2, 1997, must be proven to reduce inlet emissions of HAP by 90% or greater.	40 CFR 63.1253(c)(1)(ii)
B.3.c	Storage tanks	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	If a Control Device is an enclosed combustion device with a minimum residence time of 0.5 seconds at a minimum temperature of 760 °C.	40 CFR 63.1253 (c)(3)
B.4	Storage tanks	11, 21, 22, 41, 42, 72, 73, 74,	Emission/control standard	Planned Routine Maintenance. The requirements in 40 CFR 63.1253 (b) - (d) do not apply during	40 CFR 63.1253(e)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
		75, 81, F, 23 (Dorzolamide)		periods of planned routine maintenance. Planned maintenance shall not exceed 240 hours in any 365-day period.	
C. Process Vents - Standards					
C.1	Process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Existing Sources. For each process, the owner or operator of an existing affected source shall comply with the requirements in 63.1254 (a)(1) and (3) or with 63.1254 (a)(2) and (3). Initial compliance with the required emission limits or reductions in (a)(1) through (3) of this section shall be demonstrated in accordance with the initial compliance procedures described in 63.1257(d), and continuous compliance shall be demonstrated in accordance with the monitoring requirements described in 63.1258.	40 CFR 63.1254
C.2	Process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Existing sources may reduce all uncontrolled HAP emissions by reducing the sum of all process vents by 93% by weight.	40 CFR 63.1254 (a)(1)(i)
C.3	Process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Actual HAP emissions from all vents within a process must not exceed 900 kg (1984 lbs) in any 365-day period.	40 CFR 63.1254 (a)(2)(i)
C.4	Process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Actual HAP emissions from all processes must not exceed 1800 kg (3968 lbs) in any 365-day period.	40 CFR 63.1254 (a)(2)(ii)
C.5	Process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23	Emission/control standard	All vents subject to 40 CFR 63.1254 (a)(3) (HEV - High Emitting Vents), may be excluded in the previous sums in (a)(2)(i) and (a)(2)(ii) (C.3 and	40 CFR 63.1254 (a)(2)(iii)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
		(Dorzolamide)		C.4) above.	
C.6	Process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	Compliance with 40 CFR 63.1254(a)(1) may be switched to compliance with 40 CFR 63.1254(a)(2) after at least 1 year. Notification is required according to 40 CFR 63.1260(h).	40 CFR 63.1254 (a)(2)(iv)
C.7	Process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	HAP emissions must be reduced by 98% or controlled by the methods in 40 CFR 63.1254 (a)(1)(ii)(A-D) if the vent has uncontrolled HAP emissions exceeding 25 tpy and if the FRa is less than or equal to the FRI (using equations in rule). (HEV)□	40 CFR 63.1254 (a)(3)(i)
C.8	Process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Emission/control standard	During periods of planned or routine maintenance operator must shut down the associated process, use a back up control device that meets all requirements in 40 CFR 63.1254(a)(1-3), or opt to use the alternative standards, such as backup vent condensers.	40 CFR 63.1254 (a)(4)(i), 63.1254 (a)(4)(ii), 63.1254 (a)(4)(iii), 63.1252(h)
D. Monitoring Requirements for General, Storage Tank, and Process Vent Standards					
D.1	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	General. Except as specified in (a) (5) the procedures specified in c, (d), (e) and (f) are required to demonstrate initial compliance with 63.1253, 63.1254, 63.1256 and 63.1252(e), respectively. The provisions in (a)(2) through (3) apply to performance tests that are specified in (c), (d), and (e).	40 CFR 63.1257(a)
D.2	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	Except as provided in 40 CFR 63.1258 (b) (1)(i) (periodic monitoring) for each control device the owner or operator shall install and operate within the established parameter levels to ensure continued compliance with the standard (see	40 CFR 63.1258 (b) (1)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				Table 4 of 40 CFR 63 Subpart GGG).	
D.3	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	For control devices that control vent streams totaling less than 1 ton/yr, daily (or per batch) verification that control device is functioning properly	40 CFR 63.1258 (b) (1) (i)
D.4	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	Scrubbers. Monitor minimum scrubber liquid flow rate every 15 minutes; Monitor minimum pH once per day for caustic scrubber. Monitoring device accuracy (to within +/-10% of design flow for scrubbers. The monitoring device shall be calibrated annually.	40 CFR 63.1258 (b) (1) (ii)
D.5	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	Condensers. Unless alternative monitoring parameters are approved according to 40 CFR 63.1258(b)(4) (request of approval to monitor alternative parameters), Monitor maximum exit gas temperature every 15 minutes. Monitoring device accuracy +/-2% of temperature (or 2.5 °C if greater) for condensers; temperature-monitoring device calibrated annually.	40 CFR 63.1258 (b) (1) (iii)
D.6	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	Carbon adsorption systems. Various requirements for establishing regeneration or replacement frequency, bed regeneration requirements, and annual calibration of monitoring devices as needed (unless alternative monitoring parameters are approved according to 40 CFR 63.1258(b)(4) (request of approval to monitor alternative parameters)),.	40 CFR 63.1258 (b) (1) (iv) - (v)
D.7	General, storage tanks, and process	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23	Monitoring	Thermal incinerators (oxidizers). Monitor minimum combustion chamber exit gas temperature every 15 minutes. The temperature	40 CFR 63.1258 (b) (1) (vii) (A) and (B)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
	vents	(Dorzolamide)		monitoring device must be accurate to +/-0.75% of temperature (or 2.5 °C if greater) for TOU. The monitoring device must be calibrated annually.	
D.8	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	Operator must perform monthly visual inspections of each closed vent system bypass that is locked in the closed position (i.e. versus monitored for diversion re: flow meter or automatic valve position)	40 CFR 63.1258 (b) (1) (xi)
D.9	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	The averaging period for parametric monitoring is every 24 hours (daily), or a block average no longer than the time cycle of the batch. All readings are to be averaged except those during periods where controls are not being used to control HAP emissions	40 CFR 63.1258 (b) (2)
D.10	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	For controls with < 10 tpy HAP emissions, parametric monitoring is to be established based upon design evaluation. For large controls parametric monitoring is to be established based upon the average value from three test runs of stack testing	40 CFR 63.1258 (b) (3)(i) and (ii)
D.11	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	Requests to monitor parameters other than those specified in 40 CFR 63 Subpart GGG for control devices must be through the Precompliance Report or per 40 CFR 63.8 (f).	40 CFR 63.1258 (b) (4)
D.12	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	Exceedances for operating parameters are defined as greater than maximum or lower than minimum level for the 24-hour average value for an operating parameter.	40 CFR 63.1258 (b) (6)
D.13	General,	11, 21, 22, 41,	Monitoring	Excursions are defined by either of the two cases	40 CFR 63.1258

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
	storage tanks, and process vents	42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)		listed in 40 CFR 63.1258(b)(7)(i) or (ii) -- when more than 25% of operating hours in a day (when a device is operated for 4 or more hours that day) are not valid (i.e. the hour does not contain four 15-minute readings). For an operating day with less than 4 hours, an excursion is when the period of operation does not constitute a valid hour of data due to insufficient monitoring data.	(b) (7)
D.14	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	Violations include both exceedances and excursions as defined above. i) Limit of one violation per operating day for each monitored piece of equipment. ii) Limit of one violation per day for control devices that control multiple processes; iv) periods of time when monitoring measurements exceed the parameter values as well as periods of inadequate monitoring data do not constitute a violation if they occur during a start-up, shutdown, or malfunction, and the facility follows its start-up, shutdown, and malfunction plan.	40 CFR 63.1258 (b) (8)
D.15	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	Daily 365-day rolling summations of emissions must be calculated to processes using annual emissions limit compliance option. If a process switches to this option from 93% control, emission totals must include past 365 days.	40 CFR 63.1258 (c)
E. Testing Requirements for General, Storage Tank, and Process Vent Standards					
E.1	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Testing	All control devices shall have an initial compliance demonstration which may be (a)(1) Design evaluation or 2) Testing. Operator shall establish minimum or maximum operating	40 CFR 63.1257 (a) (1) - (3) and 63.1257(b)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				parameters for emissions sources to demonstrate compliance with the MACT standard. Note: Previous testing conducted in accordance with procedures approved by the DEQ as a synthetic minor may meet these requirements if approved to do so on a case-by-case basis.	
E. 2	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Testing	<i>Test methods.</i> When testing is conducted to measure emissions from an affected source, the test methods specified in 40 CFR 63.1257(b)(1) through (10) shall be used. Note: Previous testing conducted in accordance with procedures approved by the DEQ as a synthetic minor may meet these requirements if approved to do so on a case-by-case basis.	40 CFR 63.1257 (b)
E.3	Storage tanks	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Testing	<i>Initial compliance with storage tank provisions.</i> The owner or operator of an affected storage tank shall demonstrate initial compliance with §63.1253(b) or (c), as applicable, by fulfilling the requirements of paragraph (c)(1), or (c)(2), or (c)(3) of this section.	40 CFR 63.1257(c)
E.3	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Testing	<i>Initial compliance for mass limit process vent sources and for compliance reduction requirements</i> in 40 CFR 63.1254(a)(1)(i), (a)(3), and (b) is demonstrated according to 40 CFR 63.1257(d)(1)(ii)(A) and (B).	40 CFR 63.1257 (d) (1) (i) and (ii)
F. Recordkeeping Requirements for General, Storage Tank, and Process Vent Standards					
F.1	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Recordkeeping	Keep copies of all records and reports for 5 years (as specified in 63.10(b)(1)) - the most recent 2 years of data shall be on-site. The remaining 3 years can be off-site in formats such as computer,	40 CFR 62.1259(a)(1) and 63.10(b)(1)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				microfilm, floppy, etc.	
F.2	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Recordkeeping	Sources not subject to Subpart GGG must keep records of the applicability determination (as specified in 40 CFR 63.10(b)(3)). Keep area source determination records for 5 years or until the source changes to major.	40 CFR 63.1259(a)(2) and 63.10(b)(3)
G. Reporting Requirements for General, Storage Tank, and Process Vent Standards					
G.1	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	Submit Periodic Report semi-annually, except as required: (i) by the Administrator on a case by case basis; and (iii) when a new Operating Scenario has been operated since the last report, in which case quarterly reporting shall be submitted.	40 CFR 63.1260(g)(1)
G.2	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	As applicable, negative declarations for: excess emissions; parameter exceedances; and excursions, as specified in 40 CFR 63.1260(g)(2)(v)(A) through (C)	40 CFR 63.1260(g)(2)(v)
G.3	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	Report process changes or changes to the information provided in the Notification of Compliance Status Report in the next Periodic Report	40 CFR 63.1260(h)(1)
G.4	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	Submit a report 60 days prior to the scheduled change of any activity covered by the Precompliance Report.	40 CFR 63.1260(h)(2)(i)
G.5	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	Report SSM events in the Periodic Report, as described in 40 CFR 63.1259(a)(3)(i) and (ii), 40 CFR 63.6(e)(3)(iii) and 63.10(d)(5)(i). Report revisions made to the SSM Plan in the Periodic Report as described in 40 CFR 63.6(e)(3)(viii).	40 CFR 63.1260(i)(1)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
G.6	General, storage tanks, and process vents	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	Report actions not consistent with the SSM Plan immediately (within 2 working days) and in a follow up report (within 7 days), as described in 40 CFR 63.1259(a)(3)(iii), 40 CFR 63.6(e)(3)(IV) and 40 CFR 63.10(D)(5)(II).	40 CFR 63.1260(i)(2)
H. Equipment Leaks					
H.1	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	General Equipment Leak Requirements. (1) The provisions of this section apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems,, open -ended valves or lines, valves, connectors, instrumentation systems , control devices, and closed vent systems required by this section that are intended to operate in organic HAP service 300 hours or more during the calendar year within a source subject to the provisions of 40 CFR 63 Subpart GGG.	40 CFR 63.1255(a)(1)
H.2	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	Consistency with other regulations. Equipment subject to both 40 CFR 63.1255 and either of the following will be required to comply only with the provisions of 40 CFR 63 Subpart GGG : 40 CFR part 61 and 61.	40 CFR 63.1255(a)(2)
H.3	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	The provisions in 40 CFR 63.1(a)(3) of 40 CFR 63 Subpart A do not alter the provisions in paragraph (a)(2) of 40 CFR 63.1255	40 CFR 63.1255(a)(4)
H.4	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	Lines and equipment not containing process fluids are not subject to the provisions of 40 CFR 63.1255. Utilities, and other nonprocess lines, such as heating and cooling systems which do not	40 CFR 63.1255(a)(5)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				combine their materials with those in the processes they serve, are not considered to be a part of the process.	
H.5	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	The provisions of 40 CFR 63.1255 do not apply to bench -scale processes	40 CFR 63.1255(a)(6)
H.6	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	Equipment shall be identified such that it can be distinguished readily from equipment that is not subject to 40 CFR 63.1255. If changes are made to the affected source subject to LDAR requirements, equipment identification for each type of component shall be updated, if needed, within 90 calendar days or by the next periodic report following the end of the monitoring period for that component, whichever is later.	40 CFR 63.1255(a)(7)
H.7	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	Equipment that is in vacuum service is excluded from LDAR requirements	40 CFR 63.1255(a)(8)
H.8	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	Equipment that is in organic HAP service, but is in such service less than 300 hours per calendar year, is excluded from the LDAR requirements if it is identified as required in 40 CFR 63.1255(g)(9).	40 CFR 63.1255(a)(9)
H.9	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	When each leak is detected by visual, audible, or olfactory means, or by monitoring as described in 40 CFR 63.180(b) or (c), the following conditions apply: (i) a weather proof and readily visible identification, marked with the equipment	40 CFR 63.1255(a)(10)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				identification number, shall be attached to the leaking equipment, (ii) the identification on a valve in light liquid or gas / vapor service may be removed after it has been monitored as specified in paragraph 40 CFR 63.1255(e)(7)(iii), and no leak has been detected during the follow-up monitoring, and (iii) the identification on equipment, except on a valve in light liquid or gas/vapor service, may be removed after it has been repaired.	
H.10	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	Details concerning the definition of period of time apply.	40 CFR 63.1255(a)(11)(i) – (iv)
H.11	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	In all cases requiring repair of leaks, it is a violation to fail to take action to repair the leaks within the specified time	40 CFR 63.1255(a)(12)
H.12	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Standard/Work Practice	References. The permittee shall comply with the provisions of 40 CFR 63 Subpart H, as specified in paragraphs (b)(2) through (4) of section 40 CFR 63.1255.	40 CFR 63.1255(b)
H.13	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring, repair, recordkeeping and reporting	Standards for pumps in light liquid service and agitators in gas/vapor service and in light liquid service: (1) The monitoring, repair, recordkeeping, and reporting provisions of 63.1255(c) (2) - (9) apply upon the time the permittee becomes a major source.	40 CFR 63.1255(c)(1)
H.14	General	11, 21, 22, 41, 42, 72, 73, 74,	Monitoring, repair, recordkeeping and	Standards for open ended valves or lines. The monitoring, repair, recordkeeping, and reporting	40 CFR 63.1255(d)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
		75, 81, F, 23 (Dorzolamide)	reporting	provisions of 40 CFR 63.1255(d) (1) - (6) apply upon the time the permittee becomes a major source.	
H.15	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring, repair, recordkeeping and reporting	Standards for valves in light liquid service and in gas/vapor service. (1) The monitoring, repair, recordkeeping, and reporting provisions of 40 CFR 63.1255(e) (3) - (9) apply upon the time the permittee becomes a major source.	40 CFR 63.1255(e)
H.16	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Monitoring	Unsafe to monitor/inspect, difficult to monitor/inspect, and inaccessible equipment. Equipment that is designated as unsafe to monitor, unsafe to inspect, difficult to monitor, difficult to inspect, or inaccessible is exempt from the monitoring requirements as specified in paragraphs (f)(1)(i) - (iv) of 40 CFR 63.1255 provided the owner or operator meets the requirements specified in paragraphs (f)(2) - (4) of 40 CFR 63.1255, as applicable.	40 CFR 63.1255(f)(1)
H.17	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Recordkeeping	Recordkeeping Requirements. (1) The permittee may comply with the recordkeeping requirements for groups of processes in one recordkeeping system if the system identifies with each record the program being implemented (e.g. quarterly monitoring) for each type of equipment. All records and information required by 40 CFR 63.1255 shall be maintained in a manner that can be readily accessed at the plant site. This could include physically locating the records at the plant site or accessing the records from a central location by computer at the plant site.	40 CFR 63.1255(g)(1)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
H.18	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Recordkeeping	General recordkeeping. Except as provided in 40 CFR 63.1255(g)(5)(i) and 63.1255(a)(9) the information pertaining to all equipment subject to the requirements of 40 CFR 63.1255(g)(2)(i) through 63.1255(g)(2)(i)(viii) shall be recorded.	40 CFR 63.1255(g)(2)
H.19	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Recordkeeping	Records of visual inspections. For visual inspections of equipment subject to the provisions of paragraphs 40 CFR 63.1255(c)(2)(iii) and 63.1255(c)(5)(iv), the owner or operator shall document that the inspection was conducted and the date of the inspection. The owner or operator shall maintain records as specified in 40 CFR 63.1255(g)(4) for leaking equipment identified in this inspection, except as provided in 40 CFR 63.1255(g)(5). These records shall be retained for 2 years.	40 CFR 63.1255(g)(3)
H.20	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Recordkeeping	Monitoring records. When each leak is detected as specified in 40 CFR 63.1255(c) and 63.164, 63.1255(e) and 63.169, and 63.172 and 63.174 the information at 63.1255(g)(4)(i) through 63.1255(g)(4)(ix) shall be recorded and kept for 5 years (at least 2 years onsite, with the remaining 3 years either onsite or offsite).	40 CFR 63.1255(g)(4)
H.21	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Recordkeeping	Records of pressure tests. The owner or operator who elects to pressure test a process equipment train or supply lines between storage and processing areas to demonstrate compliance with 40 CFR 63.1255 is exempt from the requirements of 40 CFR 63.1255(g)(2),(3),(4) and (6). Instead, the owner or operator shall maintain records of	40 CFR 63.1255(g)(5)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				the information at 40 CFR 63.1255(g)(5)(i) through 63.1255(g)(5)(v).	
H.22	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Recordkeeping	Records of compressor and relief device compliance tests. The dates and results of each compliance test required for compressors subject to the provisions in 40 CFR 63.164(i) and the dates and results of the monitoring following a pressure release for each pressure relief device subject to the provisions in 40 CFR 63.165(a) and (b). The results shall include: (i) the background level measured during each compliance test. (ii) The maximum instrument reading measured at each piece of equipment during the compliance test.	40 CFR 63.1255(g)(6)
H.23	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Recordkeeping	Records for closed -vent systems. The owner or operator shall maintain records of the information specified in 40 CFR 63.1255(g)(7)(i) through (iii) for closed vent systems and control devices subject to 40 CFR 63.1255(b)(4)(ii). The records specified in 40 CFR 63.1255 (g)(7)(i) shall be retained for the life of the equipment. The records specified in 40 CFR 63.1255 (g)(7)(ii) and 63.1255 (g)(7)(iii) shall be retained for 2 years.	40 CFR 63.1255(g)(7)
H.24	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Recordkeeping	Records of exempt components. Identification, either by list, location (area or group) of equipment in organic HAP service less than 300 hours per year subject to the provisions of this section.	40 CFR 63.1255(g)(9)
H.25	General	11, 21, 22, 41,	Recordkeeping	Records of alternative means of compliance	40 CFR

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
		42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)		determination. Owners and operators choosing to comply with the requirements of 40 CFR 63.179 shall maintain the following records: (i) Identification of the process(es) and the organic HAP they handle. (ii) A schematic of the process, enclosure, and closed vent system. (iii) A description of the system used to create a negative pressure in the enclosure to ensure that all emissions are routed to the control device.	63.1255(g)(10)
H.26	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	Reporting Requirements. The permittee shall submit the reports listed in (h)(1)(i) through (ii). (i) A notification of Compliance Status Report described in (h)(2), (ii) Periodic reports described in paragraph (h)(3).	40 CFR 63.1255(h)(1)
H.27	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	Notification of compliance status report. Each owner or operator of a source subject to this section shall submit the information specified in paragraphs 40 CFR 63.1255(h)(2)(i) through 63.1255(iii) in the Notification of Compliance Status Report described in 40 CFR 63.1260(f).	40 CFR 63.1255(h)(2)
H.28	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	The notification shall provide the information listed in 40 CFR 63.1255(h)(2)(i): (A) Process group identification, (B) Number of each equipment type (e.g. valves, pumps) in organic HAP service, excluding equipment in vacuum service and (C) Method of compliance with the standard (for example, "monthly leak detection and repair" or "equipped with dual mechanical seals").	40 CFR 63.1255(h)(2)(i)
H.29	General	11, 21, 22, 41,	Reporting	Periodic reports. (i) The owner or operator shall	40 CFR

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
		42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)		submit a report containing the information in 63.1255(h)(3)(ii), (iii), and (iv). The first report shall be submitted no later than 240 days after the Notification of Compliance Status Report is due and shall cover the 6-month period beginning on the date the Notification of Compliance Status Report is due. Each subsequent report shall cover the 6-month period following the preceding period.	63.1255(h)(3)(i)
H.30	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	(ii) For equipment complying with 63.1255 (b) through (g), except (b)(4)(iv) and 63.179, the summary information listed in (h)(3)(ii)(A) through (L) for each monitoring period during the 6-month period. (A) The number of valves for which leaks were detected as described in 40 CFR 63.12.55(e)(3), the percent leakers, and the total number of valves monitored: (B) The number of valves for which leaks were not repaired as required in 40 CFR 63.1255 (e)(7), identifying the number of those that are determined nonreparable; (C) Separately, the number of pumps and agitators for which leaks were detected as described in 40 CFR 63.12.55(c)(2), the total number of pumps and agitators monitored, and for pumps, the percent leakers, (D) Separately, for the number of pumps and agitators for which leaks were not repaired as required in 40 CFR 63.1255 (c)(3), (E) The number of compressors for which leaks were detected as described in 40 CFR 63.164(f); (F)	40 CFR 63.1255(h)(3)(ii)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				The number of compressors for which leaks were not repaired as required in 40 CFR 63.164(g); (G) The number of connectors for which leaks were detected as described in 40 CFR 63.174(a), the percent of connectors leaking, and the total number of connectors monitored; (H) The number of connectors for which leaks were not repaired as required in 40 CFR 63.174(d), identifying the number of those that are determined nonrepairable; (I) The facts that explain any delay of repairs and, where appropriate, why the process shutdown was technically infeasible. (J) The results of all monitoring to show compliance with 40 CFR 63.164(i), 63.165(a), and 63.172(f) conducted within the semiannual reporting period. (K) If applicable, the initiation of a monthly monitoring program under either 40 CFR 63.1255 (c)(4)(ii) or 63.1255 (e)(4)(i). (L) If applicable, notification of a change in connector monitoring alternatives as described in 40 CFR 63.174(c)(1).	
H.31	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	For owners or operators electing to meet the requirements of 40 CFR 63.178(b), the report shall include the information listed in 40 CFR 63.1255(h)(3)(iii)(A) through (E)	40 CFR 63.1255(h)(3)(iii)
H.32	General	11, 21, 22, 41, 42, 72, 73, 74, 75, 81, F, 23 (Dorzolamide)	Reporting	Any revisions to items reported in earlier Notification of Compliance Status report, if the method of compliance has changed since the last report.	40 CFR 63.1255(h)(3)(iv)
I. Wastewater – General Standards, Monitoring, Testing, Recordkeeping and Reporting					

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
I.1	General	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Standard/work practice	(a) General. Each owner or operator of any affected source (existing or new) shall comply with the general wastewater requirements in 40 CFR 63.1256 (a) (1) through (3) and the maintenance wastewater provisions in 40 CFR 63.1256(a)(4). An owner or operator may transfer wastewater to a treatment operation not owned by the owner or operator in accordance with 63.1256 (a)(5). Note: The Merck Stonewall facility will utilize the 95 percent mass reduction option for biological treatment processes (see 40 CFR 63.1256 (g)(11) below).	40 CFR 63.1256(a)
I.2	General	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Standard/work practice	Maintenance wastewater requirements. The owner or operator of a source subject to 40 CFR 63 Subpart GGG shall comply with the requirements of 40 CFR 63.12.1256 (a)(4)(i) through (iv) for maintenance wastewater containing partially soluble or soluble HAP listed in Tables 2 and 3 of 40 CFR 63 Subpart GGG. Maintenance wastewater is exempt from all other provisions of this subpart.	40 CFR 63.1256(a)(4)
I.3	General	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Standard/work practice	Offsite treatment. The owner or operator may elect to transfer affected wastewater to an offsite treatment operation in accordance with the applicable provisions of 40 CFR 63.1256 (a)(5)(i) through (v).	40 CFR 63.1256(a)(5)
J. Wastewater: Tanks – Standards, Monitoring, Testing, Recordkeeping and Reporting					
J.1	Wastewater tanks	F (Wastewater treatment)	Standard/work practice	Each affected wastewater tank must comply with 40 CFR 63.1256 by: being equipped with a fixed	40 CFR 63.1256(b)(1)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				roof; meeting the vapor pressure and volume limits in Table 6 of 40 CFR 63 Subpart GGG; and not being heated, treated by means of an exothermic reaction or sparged. Vapor pressure shall be determined bimonthly by sampling and calculation of organic HAP vapor pressure. Compliance with 40 CFR 63.1256(b)(1) shall be demonstrated by a calculated vapor pressure <5.2kPa and the wastewater tank design volume.	
J.2	Wastewater tanks	F (Wastewater treatment)	Monitoring	Each affected wastewater tank shall be visually inspected initially and semi-annually, as specified in Table 7 of 40 CFR 63 Subpart GGG, including; inspecting all fixed roofs, and openings for visible, audible or olfactory leaks; and for improper work practices (connections opened when not in use).	40 CFR 63.1258(g)(1)
J.3	Wastewater tanks	F (Wastewater treatment)	Monitoring	Leak inspection provisions for vapor suppression equipment. Except as provided in (h)(9) and (10) of this section, for each vapor collection system, closed -vent system, fixed roof, cover, or enclosure required to comply with this section, the owner or operator shall comply with the requirements of 40 CFR 63.1258(h)(2) through (8). Leaks or improper work practices found by the visual inspection in 40 CFR 63.1258(g)(1) shall be repaired as soon as possible, with the first attempt at repair no later than 5 calendar days after the leak is detected.	40 CFR 63.1258(h)
J.4	Wastewater tanks	F (Wastewater treatment)	Recordkeeping	<i>Requirements of 40 CFR 63 Subpart A.</i> The owner or operator of an affected source shall	40 CFR 63.1259(a)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				comply with the recordkeeping requirements in 40 CFR 63 Subpart A as specified in Table 1 of 40 CFR 63 Subpart GGG and in paragraphs (a)(1) through (5) of 40 CFR 63.1259.	
J.5	Wastewater tanks	F (Wastewater treatment)	Recordkeeping	Maintain copies of all records and reports required to demonstrate compliance for at least 5 years.	40 CFR 63.1259(a)(1)
J.6	Wastewater tanks	F (Wastewater treatment)	Recordkeeping	Records associated with the SSM Plan (including revisions) and all related SSM events as described in 40 CFR 63.6.(e)(3), including: occurrence and duration of SSM events of process, emission control and monitoring equipment; and corrective actions taken that were or were not consistent with the SSM Plan.	40 CFR 63.1259(a)(3)
J.7	Wastewater tanks	F (Wastewater treatment)	Recordkeeping	Maintain a record of the calculated vapor pressure and tank design volume to demonstrate compliance with 40 CFR 63.1256(b)(1) on a bimonthly basis	40 CFR 63.1259(b)(9)
J.8	Wastewater tanks	F (Wastewater treatment)	Recordkeeping	Maintain a record of the visual inspections of all affected wastewater tanks described in 40 CFR 63.1258(g)(1) (including Table 7 of 40 CFR 63 Subpart GGG)	40 CFR 63.1259(i)(1)
J.9	Wastewater tanks	F (Wastewater treatment)	Recordkeeping	For each visual inspection conducted in accordance with 40 CFR 63.1258 (h)(2)(i)(B) or (h)(2)(iii)(B) in which a leak is detected, record the: (i) leaking equipment; (iii) date the leak was detected and the date of the first attempt to repair the leak; (v) through (viii) information addressing any delay of repair of the leak; and (ix) the completion date of repair.	40 CFR 63.1259(i)(7)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
J.10	Wastewater tanks	F (Wastewater treatment)	Recordkeeping	For each visual inspection of affected wastewater tanks described in 40 CFR 63.1258(g)(1) in which a leak is not detected, record that the inspection was performed, the date of the inspection and that no leaks were detected.	40 CFR 63.1259(i)(9)
J.11	Wastewater tanks	F (Wastewater treatment)	Reporting	The owner or operator of an affected source shall comply with the reporting requirements of paragraphs (b) through (l) of 40 CFR 63.1260.	40 CFR 63.1260(a)
J.12	Wastewater tanks	F (Wastewater treatment)	Reporting	Submit Periodic Report semi-annually, except as required: (i) by the Administrator on a case by case basis; and (iii) when a new Operating Scenario has been operated since the last report, in which case quarterly reporting shall be submitted.	40 CFR 63.1260(g)(1)
J.13	Wastewater tanks	F (Wastewater treatment)	Reporting	For each visual inspection of affected wastewater tanks described in 40 CFR 63.1258(g)(1) in which a leak is detected, submit the record specified in 40 CFR 63.1259(i)(7) in the next Periodic Report.	40 CFR 63.1260(g)(2)(iii)
J.14	Wastewater tanks	F (Wastewater treatment)	Reporting	As applicable, negative declarations for: excess emissions; parameter exceedances; and excursions, as specified in 40 CFR 63.1260(g)(2)(v)(A) through (C).	40 CFR 63.1260(g)(2)(v)
J.15	Wastewater tanks	F (Wastewater treatment)	Reporting	Verification that each new Operating Scenario, which has been operated since the time period covered by the last Periodic Report or the Notification of Compliance Status Report, has not exceeded the operating conditions of the wastewater tank controls.	40 CFR 63.1260(g)(2)(vii)
J.16	Wastewater	F (Wastewater	Reporting	Report process changes or changes to the	40 CFR

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
	tanks	treatment)		information provided in the Notification of Compliance Status Report in the next Periodic Report	63.1260(h)(1)
J.17	Wastewater tanks	F (Wastewater treatment)	Reporting	Submit a report 60 days prior to the schedule change of any activity covered by the Precompliance Report.	40 CFR 63.1260(h)(2)(i)
J.18	Wastewater tanks	F (Wastewater treatment)	Reporting	Report SSM events in the Periodic Report, as described in 40 CFR 63.1259(a)(3)(i) and (ii), 63.6(e)(3)(iii) and 63.10(d)(5)(i). Report revisions made to the SSM Plan in the Periodic Report as described in 40 CFR 63.6(e)(3)(viii).	40 CFR 63.1260(i)(1)
J.19	Wastewater tanks	F (Wastewater treatment)	Reporting	Report actions not consistent with the SSM Plan immediately (within 2 working days) and in a follow up report (within 7 days), as described in 63.1259(a)(3)(iii), 63.6(e)(3)(IV) AND 63.10(D)(5)(II).	40 CFR 63.1260(i)(2)
J.20	Wastewater tanks	F (Wastewater treatment)	Monitoring	Leak inspection provisions for vapor suppression equipment. Except as provided in 40 CFR 63.1258(h)(9) and (10), for each vapor collection system, closed -vent system, fixed roof, cover, or enclosure required to comply with this section, the owner or operator shall comply with the requirements of 40 CFR 63.1258(h)(2) through (8). Leaks or improper work practices found by the visual inspection in 40 CFR 63.1258(g)(1) shall be repaired as soon as possible, with the first attempt at repair no later than 5 calendar days after the leak is detected.	40 CFR 63.1258(h)
K. Wastewater: Containers – Standards, Monitoring, Testing, Recordkeeping and Reporting					
K.1	Wastewater	F (Wastewater	Standard/work	All covers and openings (e.g. hatches, sample	40 CFR

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
	containers	treatment)	practice	ports) on Large containers (>110 gallons) shall be maintained without leaks.	63.1256(d)(1)(i)
K.2	Wastewater containers	F (Wastewater treatment)	Standard/work practice	All Small Containers (<= 110 gallons) must meet applicable Department of Transportation (DOT) specifications and testing, or all covers and openings shall be maintained without leaks.	40 CFR 63.1256(d)(1)(ii)
K.3	Wastewater containers	F (Wastewater treatment)	Standard/work practice	Covers and openings (e.g. hatches, sample ports) on all containers shall be maintained in a closed position at all times except when in use for sampling, inspections, maintenance repairs, etc.	40 CFR 63.1256(d)(1)(iii)
K.4	Wastewater containers	F (Wastewater treatment)	Standard/work practice	<i>Filling of Large Containers.</i> Pumping affected wastewater or a residual removed from affected wastewater into a container with a capacity greater than or equal to 0.42 m ³ shall be conducted in accordance with the following: (A) use a submerged fill pipe no more than 6" or two pipe diameters from the container bottom; (B) vent emissions to a control device; or (C) vent emission back to the wastewater source. All covers and openings on the container shall be maintained in a closed position during filling, except for the fill pipe and vent (if needed).	40 CFR 63.1256(d)(2)
K.5	Wastewater containers	F (Wastewater treatment)	Monitoring	Each affected container shall be visually inspected initially and semiannually, as specified in 40 CFR 63.1258(g)(1) and Table 7 of 40 CFR 63 Subpart GGG, including; inspecting all covers and opening for visible, audible, or olfactory leaks (broken or cracked joint, lid, cover or gasket that is broken, cracked or has a gap); and for improper work practices (covers or	40 CFR 63.1256(d)(4)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				connections opened when not in use).	
K.6	Wastewater containers	F (Wastewater treatment)	Standard/work practice	Leaks or improper work practices found by visual inspection in 40 CFR 63.1256(d)(4) shall be repaired as soon as practicable, with the first attempt at repair no later than 5 calendar days after the leak is detected, and completed no later than 15 days after the leak is detected.	40 CFR 63.1256(d)(5)
K.7	Wastewater containers	F (Wastewater treatment)	Monitoring	Each affected wastewater container shall be visually inspected initially and semi-annually, as specified in Table 7 of 40 CFR 63 Subpart GGG, including; inspecting all fixed roofs, and openings for visible, audible or olfactory leaks; and for improper work practices (connections opened when not in use).	40 CFR 63.1258(g)(1)
K.8	Wastewater containers	F (Wastewater treatment)	Monitoring	Leak inspection provisions for vapor suppression equipment. Except as provided in 40 CFR 63.1258(h)(9) and (10), for each vapor collection system, closed -vent system, fixed roof, cover, or enclosure required to comply with this section, the owner or operator shall comply with the requirements of 40 CFR 63.1258(h)(2) through (8). Leaks or improper work practices found by the visual inspection in 40 CFR 63.1258(g)(1) shall be repaired as soon as possible, with the first attempt at repair no later than 5 calendar days after the leak is detected.	40 CFR 63.1258(h)
K.9	Wastewater containers	F (Wastewater treatment)	Recordkeeping	<i>Requirements of 40 CFR 63 Subpart A.</i> The owner or operator of an affected source shall comply with the recordkeeping requirements in 40 CFR 63 Subpart A as specified in Table 1 of	40 CFR 63.1259(a)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				40 CFR 63 Subpart GGG and in paragraphs (a)(1) through (5) of 40 CFR 63.1259.	
K.10	Wastewater containers	F (Wastewater treatment)	Recordkeeping	Maintain copies of all records and reports required to demonstrate compliance for at least 5 years.	40 CFR 63.1259(a)(1)
K.11	Wastewater containers	F (Wastewater treatment)	Recordkeeping	Records associated with the SSM Plan (including revisions) and all related SSM events as described in 40 CFR 63.6.(e)(3), including: occurrence and duration of SSM events of process, emission control and monitoring equipment; and corrective actions taken that were or were not consistent with the SSM Plan.	40 CFR 63.1259(a)(3)
K.12	Wastewater containers	F (Wastewater treatment)	Recordkeeping	Maintain a record of the visual inspections of all affected wastewater tanks described in 40 CFR 63.1256(d)(4)	40 CFR 63.1259(i)(1)
K.13	Wastewater containers	F (Wastewater treatment)	Recordkeeping	For each visual inspection of affected wastewater tanks described in 40 CFR 63.1258(g)(1) in which a leak is detected, record the: (i) leaking equipment; (iii) date the leak was detected and the date of the first attempt to repair the leak; (v) through (viii) information addressing any delay of repair of the leak; and (ix) the completion date of repair.	40 CFR 63.1259(i)(7)
K.14	Wastewater containers	F (Wastewater treatment)	Recordkeeping	For each visual inspection conducted in accordance with 40 CFR 63.1258 (h)(2)(i)(B) or (h)(2)(iii)(B) in which a leak is not detected, record that the inspection was performed, the date of the inspection and that no leaks were detected.	40 CFR 63.1259(i)(9)
K.15	Wastewater	F (Wastewater	Reporting	The owner or operator of an affected source shall	40 CFR 63.1260

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
	containers	treatment)		comply with the reporting requirements of paragraphs 40 CFR 63.1260(b) through (l) of this section.	(a)
K.16	Wastewater containers	F (Wastewater treatment)	Reporting	Submit Periodic Report semi-annually, except as required: (i) by the Administrator on a case by case basis; and (iii) when a new Operating Scenario has been operated since the last report, in which case quarterly reporting shall be submitted.	40 CFR 63.1260(g)(1)
K.17	Wastewater containers	F (Wastewater treatment)	Reporting	For each visual inspection of affected wastewater tanks described in 40 CFR 63.1258(g)(1) in which a leak is detected, submit the record specified in 40 CFR 63.1259(i)(7) in the next Periodic Report.	40 CFR 63.1260(g)(2)(iii)
K.18	Wastewater containers	F (Wastewater treatment)	Reporting	Report process changes or changes to the information provided in the Notification of Compliance Status Report in the next Periodic Report	40 CFR 63.1260(h)(1)
K.19	Wastewater containers	F (Wastewater treatment)	Reporting	Submit a report 60 days prior to the schedule change of any activity covered by the Precompliance Report.	40 CFR 63.1260(h)(2)(i)
K.20	Wastewater containers	F (Wastewater treatment)	Reporting	Report SSM events in the Periodic Report, as described in 40 CFR 63.1259(a)(3)(i) and (ii), 63.6(e)(3)(iii) and 63.10(d)(5)(i). Report revisions made to the SSM Plan in the Periodic Report as described in 40 CFR 63.6(e)(3)(viii).	40 CFR 63.1260(i)(1)
K.21	Wastewater containers	F (Wastewater treatment)	Reporting	Report actions not consistent with the SSM Plan immediately (within 2 working days) and in a follow up report (within 7 days), as described in 40 CFR 63.1259(a)(3)(iii), 63.6(e)(3)(IV) and	40 CFR 63.1260(i)(2)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
				63.10(D)(5)(II).	
L. Wastewater: Individual Drain Systems – Standards, Monitoring, Testing, Recordkeeping and Reporting					
L.1	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Standard/work practice	Individual drain systems. For each individual drain system that receives or manages affected wastewater or a residual removed from affected wastewater, the owner or operator shall comply with the requirements of (e) (1) through (3) or with (e) (4) through (6) of 40 CFR 63.1256.	40 CFR 63.1256 (e)
L.2	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Monitoring	Each affected wastewater individual drain system shall be visually inspected initially and semi-annually, as specified in Table 7 of 40 CFR 63 Subpart GGG, including; inspecting all fixed roofs, and openings for visible, audible or olfactory leaks; and for improper work practices (connections opened when not in use).	40 CFR 63.1258(g)(1)
L.3	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Recordkeeping	Requirements of 40 CFR 63 Subpart A. The owner or operator of an affected source shall comply with the recordkeeping requirements in 40 CFR 63 Subpart A as specified in Table 1 of 40 CFR 63 Subpart GGG and in paragraphs (a)(1) through (5) of 40 CFR 63.1259.	40 CFR 63.1259(a)
L.4	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Recordkeeping	Maintain copies of all records and reports required to demonstrate compliance for at least 5 years.	40 CFR 63.1259(a)(1)
L.5	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42,	Recordkeeping	Records associated with the SSM Plan (including revisions) and all related SSM events as described in 40 CFR 63.6(e)(3), including:	40 CFR 63.1259(a)(3)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
		72, 73, 74, 75, 81, 23 (Dorzolamide)		occurrence and duration of SSM events of process, emission control and monitoring equipment; and corrective actions taken that were or were not consistent with the SSM Plan.	
L.6	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Recordkeeping	Maintain a record of the visual inspections of all affected wastewater tanks described in 40 CFR 63.1256(d)(4)	40 CFR 63.1259(i)(1)
L.7	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Recordkeeping	For each visual inspection conducted in accordance with 40 CFR 63.1258 (h)(2)(i)(B) or (h)(2)(iii)(B) in which a leak is detected, record the: (i) leaking equipment; (iii) date the leak was detected and the date of the first attempt to repair the leak; (v) through (viii) information addressing any delay of repair of the leak; and (ix) the completion date of repair.	40 CFR 63.1259(i)(7)
L.8	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Recordkeeping	For each visual inspection of affected wastewater tanks described in 40 CFR 63.1258(g)(1) in which a leak is not detected, record that the inspection was performed, the date of the inspection and that no leaks were detected.	40 CFR 63.1259(i)(9)
L.9	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Reporting	Submit Periodic Report semi-annually, except as required: (i) by the Administrator on a case by case basis; and (iii) when a new Operating Scenario has been operated since the last report, in which case quarterly reporting shall be submitted.	40 CFR 63.1260(g)(1)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
L.10	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Reporting	For each visual inspection of affected wastewater tanks described in 40 CFR 63.1258(g)(1) in which a leak is detected, submit the record specified in 40 CFR 63.1259(i)(7) in the next Periodic Report.	40 CFR 63.1260(g)(2)(iii)
L.11	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Reporting	Report process changes or changes to the information provided in the Notification of Compliance Status Report in the next Periodic Report	40 CFR 63.1260(h)(1)
L.12	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Reporting	Submit a report 60 days prior to the schedule change of any activity covered by the Precompliance Report.	40 CFR 63.1260(h)(2)(i)
L.13	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Reporting	Report SSM events in the Periodic Report, as described in 40 CFR 63.1259(a)(3)(i) and (ii), 63.6(e)(3)(iii) and 63.10(d)(5)(i). Report revisions made to the SSM Plan in the Periodic Report as described in 40 CFR 63.6(e)(3)(viii).	40 CFR 63.1260(i)(1)
L.14	Wastewater treatment, general	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Reporting	Report actions not consistent with the SSM Plan immediately (within 2 working days) and in a follow up report (within 7 days), as described in 40 CFR 63.1259(a)(3)(iii), 63.6(e)(3)(IV) and 63.10(D)(5)(II).	40 CFR 63.1260(i)(2)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
M. Wastewater Standards: 95% Organic HAP Control Option					
M.1	Wastewater treatment	F (Wastewater treatment)	Standard/work practice	Performance standards for treatment processes managing wastewater and/or residuals removed from wastewaters. The owner or operator shall comply with the requirements as specified in 40 CFR 63.1256 (g)(1) through (6). Where multiple compliance options are provided, the options may be used in combination for different wastewater and/or for different compounds (e.g. soluble versus partially soluble compounds) in the same wastewater, except where otherwise provided	40 CFR 12.1256(g)
M.2	Wastewater treatment	F (Wastewater treatment)	Standard/work practice	95 - percent mass reduction option, for biological treatment processes. The owner or operator of a new or existing source using biological treatment for any affected wastewater shall reduce the mass of total soluble and partially soluble HAP sent to that biological treatment unit by at least 95%. All wastewater as defined in 40 CFR 63.1251 entering such a biological treatment unit from PMPU's subject to this subpart shall be included in the demonstration of the 95-percent mass removal. The owner or operator shall comply with 40 CFR 63.1256(g)(11)(i) through (iv).	40 CFR 63.1256(g)(11)
M.3	Wastewater treatment	F (Wastewater treatment)	Standard/work practice	Except as provided in 40 CFR 63.1256(g)(11)(iv) the owner or operator shall ensure that all wastewater from PMPU's subject to this subpart entering the biological treatment unit are treated to destroy at least 95 percent total mass of all soluble and partially soluble HAP compounds.	40 CFR 63.1256(g)(11)(i)
M.4	Wastewater	F (Wastewater	Standard/work	Compliance with the 95% total organic HAP	40 CFR

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
	treatment	treatment)	practice	destruction shall be determined using the applicable procedures described in 40 CFR 63.1257(e).	63.1256(g)(11)(ii)
M.5	Wastewater treatment	F (Wastewater treatment)	Standard/work practice	-The wastewater treatment process must comply with the applicable emission control and work practice requirements in accordance with 40 CFR 63.1256(b), (d) and (e) tanks, containers and individual drain systems, respectively.	40 CFR 63.1256(g)(11)(iii)
M.6	Wastewater treatment	F (Wastewater treatment)	Monitoring	At least weekly, measure and record the biomass concentration in the aeration tank (MLVSS), effluent total suspended solids (TSS), and 5 -day biochemical oxygen demand (BOD) of the influent and treated effluent. Bimonthly, measure and record the inlet organic HAP concentrations and calculate total organic HAP % destruction using the procedures in 40 CFR 63.1257(e)(2)(iii)(E)(3)(i) and (4)(ii), and as described in the Wastewater Treatment Performance Test Report submitted in the Notification of Compliance Status Report required by 40 CFR 63.1260(f)(2). Compliance shall be demonstrated by a MLVSS > 1000 mg/l for all samples and a monthly total organic HAP destruction >= 95%.	40 CFR 63.1258(g)(2)
M.7	Wastewater treatment	F (Wastewater treatment)	Recordkeeping	Requirements of 40 CFR 63 Subpart A. The owner or operator of an affected source shall comply with the recordkeeping requirements in subpart A of this part as specified in Table 1 of 40 CFR 63 Subpart GGG and in paragraphs (a)(1) through (5) of 40 CFR 63.1259.	40 CFR 63.1259(a)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
M.8	Wastewater treatment	F (Wastewater treatment)	Recordkeeping	Maintain copies of all records and reports required to demonstrate compliance for at least 5 years.	40 CFR 63.1259(a)(1)
M.9	Wastewater treatment	F (Wastewater treatment)	Recordkeeping	Records associated with the SSM Plan (including revisions) and all related SSM events as described in 40 CFR 63.6.(e)(3), including: occurrence and duration of SSM events of process, emission control and monitoring equipment; and corrective actions taken that were or were not consistent with the SSM Plan.	40 CFR 63.1259(a)(3)
M.10	Wastewater treatment	F (Wastewater treatment)	Recordkeeping	Records of all (at least weekly) measurements of biomass concentration in the aeration tank (MLVSS), effluent total suspended solids (TSS), and 5-day biochemical oxygen demand(BOD) of the influent and treated effluent. Records of bimonthly inlet organic HAP concentrations and calculated total organic HAP % destruction.	40 CFR 63.1259(b)(1)
M.11	Wastewater treatment	F (Wastewater treatment)	Recordkeeping	Maintain a record of the visual inspections of all affected wastewater tanks described in 40 CFR 63.1258(g)(1) (including Table 7 in 40 CFR 63 Subpart GGG)	40 CFR 63.1259(i)(1)
M.12	Wastewater treatment	F (Wastewater treatment)	Recordkeeping	For each visual inspection conducted in accordance with 40 CFR 63.1258 (h)(2)(i)(B) or (h)(2)(iii)(B) in which a leak is detected, record the: (i) leaking equipment; (iii) date the leak was detected and the date of the first attempt to repair the leak; (v) through (viii) information addressing any delay of repair of the leak; and (ix) the completion date of repair.	40 CFR 63.1259(i)(7)
M.13	Wastewater	F (Wastewater	Recordkeeping	For each visual inspection of affected wastewater	40 CFR

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
	treatment	treatment)		tanks described in 40 CFR 63.1258(g)(1) in which a leak is not detected, record that the inspection was performed, the date of the inspection and that no leaks were detected.	63.1259(i)(9)
M.14	Wastewater treatment	F (Wastewater treatment)	Reporting	Submit Periodic Report semi-annually, except as required: (i) by the Administrator on a case by case basis; and (iii) when a new Operating Scenario has been operated since the last report, in which case quarterly reporting shall be submitted.	40 CFR 63.1260(g)(1)
M.15	Wastewater treatment	F (Wastewater treatment)	Reporting	Summary Report of the wastewater treatment process parameters (MLVSS, TSS, BOD, influent HAP concentration, and calculated total organic HAP% destruction) monitoring results addressing the applicable elements in 40 CFR 63.10(e)(3)(vi) in each Periodic Report.	40 CFR 63.1260(g)(2)(i)
M.16	Wastewater treatment	F (Wastewater treatment)	Reporting	Additional reporting is required if the duration of excess emissions, parameter exceedances or excursions are $\geq 1\%$ or wastewater treatment process parameters downtime is $\geq 5\%$ of the operating time.	40 CFR 63.1260(g)(2)(ii)
M.17	Wastewater treatment	F (Wastewater treatment)	Reporting	For each visual inspection of affected wastewater tanks described in 40 CFR 63.1258(g)(1) in which a leak is detected, submit the record specified in 40 CFR 63.1259(i)(7) in the next Periodic Report.	40 CFR 63.1260(g)(2)(iii)
M.18	Wastewater treatment	F (Wastewater treatment)	Reporting	As applicable, negative declarations for: excess emissions; parameter exceedances; and excursions, as specified in 40 CFR 63.1260(g)(2)(v)(A) through (C).	40 CFR 63.1260(g)(2)(v)

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
M.19	Wastewater treatment	F (Wastewater treatment)	Reporting	Verification that each new Operating Scenario, which has been operated since the time period covered by the last Periodic Report or the Notification of Compliance Status Report, has not exceeded the operating conditions of the wastewater tank controls.	40 CFR 63.1260(g)(2)(vii)
M.20	Wastewater treatment	F (Wastewater treatment)	Reporting	Report process changes or changes to the information provided in the Notification of Compliance Status Report in the next Periodic Report	40 CFR 63.1260(h)(1)
M.21	Wastewater treatment	F (Wastewater treatment)	Reporting	Submit a report 60 days prior to the schedule change of any activity covered by the Precompliance Report.	40 CFR 63.1260(h)(2)(i)
M.22	Wastewater treatment	F (Wastewater treatment)	Reporting	Report SSM events in the Periodic Report, as described in 40 CFR 63.1259(a)(3)(i) and (ii), 63.6(e)(3)(iii) and 63.10(d)(5)(i). Report revisions made to the SSM Plan in the Periodic Report as described in 40 CFR 63.6(e)(3)(viii).	40 CFR 63.1260(i)(1)
M.23	Wastewater treatment	F (Wastewater treatment)	Reporting	Report actions not consistent with the SSM Plan immediately (within 2 working days) and in a follow up report (within 7 days), as described in 40 CFR 63.1259(a)(3)(iii), 63.6(e)(3)(IV) and 63.10(D)(5)(II).	40 CFR 63.1260(i)(2)
N. General Recordkeeping Requirements					
N.1	General	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Recordkeeping	The source shall comply with the recordkeeping requirements of 40 CFR 63.1259.	40 CFR 63.1259

Number	Area of applicability	Unit reference number	Type of requirement	Requirement	Citation
O. General Reporting Requirements					
O.1	General	F (Wastewater treatment), 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23 (Dorzolamide)	Reporting	The source shall comply with the reporting requirements of 40 CFR 63.1260.	40 CFR 63.1260

Insignificant Emission Units

The following emission units at the facility are identified in the application as insignificant emission units under 9 VAC 5-80-720:

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
CE-511	Centrifuge operations	9 VAC 5-80-720 B	PM/PM-10
RE-506	Sodium bisulfate charge	9 VAC 5-80-720 B	PM/PM-10
RE-508	NaCN charge	9 VAC 5-80-720 B	PM/PM-10
RE-601/RE-601A	Hydrazinonitrile charge	9 VAC 5-80-720 B	PM/PM-10
TA-73	Breathing and filling emissions (HCl)	9 VAC 5-80-720 B	PM/PM-10*
TA-701	Batch processing (HCl present)	9 VAC 5-80-720 B	PM/PM-10*
ST-604 TA-608 VJ-609	Batch processing (HCl present)	9 VAC 5-80-720 B	PM/PM-10*
TA-621	HCl distillates	9 VAC 5-80-720 B	PM/PM-10*
TA-606	Filling with washes containing HCl	9 VAC 5-80-720 B	PM/PM-10*
TA-710	Filling emissions (HCl present)	9 VAC 5-80-720 B	PM/PM-10*
TA-704	Disodium EDTA charge	9 VAC 5-80-720 B	PM/PM-10
TA-703 DC-703	Carbon charge	9 VAC 5-80-720 B	PM/PM-10
DR-913	Batch drying	9 VAC 5-80-720 B	PM/PM-10
MI-916	Milling	9 VAC 5-80-720 B	PM/PM-10
BN-917	Blending	9 VAC 5-80-720 B	PM/PM-10
FD-850 DC-836	Packaging from FD-850	9 VAC 5-80-720 B	PM/PM-10
SCR-601	Buggy charge to ST-901	9 VAC 5-80-720 B	PM/PM-10
FD-850 DC-850	Batch drying	9 VAC 5-80-720 B	PM/PM-10
CE-821	Centrifuge operations	9 VAC 5-80-720 B	PM/PM-10
DR-914	Batch drying	9 VAC 5-80-720 B	PM/PM-10
DI-910	Charge of material recovered from PF-929 A/B	9 VAC 5-80-720 B	PM/PM-10
Buggy	Centrifuge buggy charge to ST-901	9 VAC 5-80-720 B	PM/PM-10
DR-713	Drying of Carbidopa seed	9 VAC 5-80-720 B	PM/PM-10
TA-1108 GB-1108	Picolyl chloride charge	9 VAC 5-80-720 B	PM/PM-10
FD-1206	Batch filtration	9 VAC 5-80-720 B	PM/PM-10
TOU-2542/SCR-2546	Combustion of natural gas	9 VAC 5-80-720 B	PM/PM-10

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
HP-2604	Sodium sulfate charge Sodium chloride charge	9 VAC 5-80-720 B	PM/PM-10
HP-2606	Citric acid charge Oxoester charge	9 VAC 5-80-720 B	PM/PM-10
HP-2612	Sodium bicarbonate charge	9 VAC 5-80-720 B	PM/PM-10
HP-2614	Potassium bicarbonate charge	9 VAC 5-80-720 B	PM/PM-10
HP-2616	Sodium sulfite charge	9 VAC 5-80-720 B	PM/PM-10
HP-2721	Lithium hydroxide charge	9 VAC 5-80-720 B	PM/PM-10
HP-2721A	Rework charge	9 VAC 5-80-720 B	PM/PM-10
TA-2604	Sodium sulfate charge Sodium chloride charge	9 VAC 5-80-720 B	PM/PM-10
TA-2612	Sodium bicarbonate charge	9 VAC 5-80-720 B	PM/PM-10
TA-2614	Potassium bicarbonate charge	9 VAC 5-80-720 B	PM/PM-10
TA-2616	Sodium sulfite charge	9 VAC 5-80-720 B	PM/PM-10
BD-1552	Packaging batches	9 VAC 5-80-720 B	PM/PM-10
CE-1200	Cake discharge to bin	9 VAC 5-80-720 B	PM/PM-10
CE-1400	Cake discharge to bin	9 VAC 5-80-720 B	PM/PM-10
GB-2242	cis-Aminoindanol charge	9 VAC 5-80-720 B	PM/PM-10
RE-2242	cis-Aminoindanol charge Monoaldehyde charge	9 VAC 5-80-720 B	PM/PM-10
TA-2721	Sodium bicarbonate charge Filter aid charge Ammonium acetate charge Lithium hydroxide charge	9 VAC 5-80-720 B	PM/PM-10
TA-2606	Citric acid charge	9 VAC 5-80-720 B	PM/PM-10
TA-1277	Monohydrate seed charge	9 VAC 5-80-720 B	PM/PM-10
TA-1263	Monohydrate seed charge	9 VAC 5-80-720 B	PM/PM-10
RE-1267	Boc-piperazine charge Vacumax discharge	9 VAC 5-80-720 B	PM/PM-10
RE-1269	Boc-piperazine charge Vacumax discharge	9 VAC 5-80-720 B	PM/PM-10
RE-1425	Processing emissions (HCl)	9 VAC 5-80-720 B	PM/PM-10*
CR-1205	Palladium charge	9 VAC 5-80-720 B	PM/PM-10
CR-1281	Seed charge	9 VAC 5-80-720 B	PM/PM-10
GB-2270	Sodium borohydride charge	9 VAC 5-80-720 B	PM/PM-10
RE-2275	CaCl ₂ charge for brine make-up	9 VAC 5-80-720 B	PM/PM-10
TA-106	Nutrient charges	9 VAC 5-80-720 B	PM/PM-10
F-14	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-15	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-16	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-17	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-3	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-4	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-5	Fermentation	9 VAC 5-80-720 B	VOC / PM-10

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
G-6	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-7	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-8	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-9	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-10	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-11	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-12	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-13	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-14	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-15	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-16	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-27	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-28	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-29	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-30	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-31	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-32	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-34	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-1	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-2	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-3	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-4	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-5	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-10	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-11	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-12	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-17	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-18	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-24	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-25	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-26	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-1	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-2	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
RE-221	Sodium carbonate charge	9 VAC 5-80-720 B	PM/PM-10
TA-800	Non-sterile Cilastatin charge	9 VAC 5-80-720 B	PM/PM-10
FD-845 DC-845 VP-1075 VP-1075-1 VJ-472C	Batch drying (roughing phase and final phase)	9 VAC 5-80-720 B	PM/PM-10
MI-855	Milling operations	9 VAC 5-80-720 B	PM/PM-10
GB-860	Product packaging	9 VAC 5-80-720 B	PM/PM-10
VP-1040	Batch drying (roughing phase)	9 VAC 5-80-720 B	PM/PM-10
VP-1041	Batch drying (final phase)	9 VAC 5-80-720 B	PM/PM-10

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
VP-1050	Batch drying (roughing phase)	9 VAC 5-80-720 B	PM/PM-10
VP-1051	Batch drying (final phase)	9 VAC 5-80-720 B	PM/PM-10
GB-760	Product packaging	9 VAC 5-80-720 B	PM/PM-10
GB-765	Product packaging	9 VAC 5-80-720 B	PM/PM-10
TA-714	Non-sterile Imipenem charge	9 VAC 5-80-720 B	PM/PM-10
MI-900	Milling operations	9 VAC 5-80-720 B	PM/PM-10
GB-930	Product packaging	9 VAC 5-80-720 B	PM/PM-10
TA-725	Charge Cilastatin/Imipenem blended mixture for recovery	9 VAC 5-80-720 B	PM/PM-10
WS-508	Subdivision booth	9 VAC 5-80-720 B	PM/PM-10
FD-9900 VP-9950	Batch drying	9 VAC 5-80-720 B	PM/PM-10
WS-9900	Subdivide pure intermediate Subdivide phenyl boric acid Subdivide OS1 intermediate Subdivide samples Subdivide bulk API	9 VAC 5-80-720 B	PM/PM-10
GB-9605	Charge crude intermediate Charge proline Charge phenyl boronic acid Charge OS1 intermediate Charge seed	9 VAC 5-80-720 B	PM/PM-10
ST-9800	Charge crude intermediate Charge proline Charge sodium acetate	9 VAC 5-80-720 B	PM/PM-10
EF-9075	Subdivide silica Subdivide proline Subdivide sodium acetate Subdivide kromasil Subdivide sodium metabisulfate	9 VAC 5-80-720 B	PM/PM-10
TA-9754 funnel TA-9754	Charge silica	9 VAC 5-80-720 B	PM/PM-10
ST-9600	Charge pure intermediate Charge phenyl boronic acid Charge OS1 intermediate Charge seed	9 VAC 5-80-720 B	PM/PM-10
BT-9615	Charge triflic acid Charge 2N HCl	9 VAC 5-80-720 B	PM/PM-10*
TA-9700	Charge sodium metabisulfite	9 VAC 5-80-720 B	PM/PM-10
ST-9700	Charge sodium metabisulfite	9 VAC 5-80-720 B	PM/PM-10
FD-9980	Batch drying	9 VAC 5-80-720 B	PM/PM-10
Antibiotic filling line	Vial filling	9 VAC 5-80-720 B	PM/PM-10
Antibiotic	Powder consolidation	9 VAC 5-80-720 B	PM/PM-10

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
blending			
MX-121	Blending	9 VAC 5-80-720 B	PM/PM-10
HO-122	Hopper	9 VAC 5-80-720 B	PM/PM-10
HB-122	Pregnant chute	9 VAC 5-80-720 B	PM/PM-10
MX-185	Blending	9 VAC 5-80-720 B	PM/PM-10
HO-221	Hopper	9 VAC 5-80-720 B	PM/PM-10
HO-201	Hopper	9 VAC 5-80-720 B	PM/PM-10
IBC for MI-125	Filling of intermediate bulk container	9 VAC 5-80-720 B	PM/PM-10
EM-201	Encapsulator	9 VAC 5-80-720 B	PM/PM-10
EM-202	Encapsulator	9 VAC 5-80-720 B	PM/PM-10
EM-221	Encapsulator	9 VAC 5-80-720 B	PM/PM-10
Lakso filler	Bottle filling	9 VAC 5-80-720 B	PM/PM-10
Crixivan house vacuum	Equipment cleanup activities	9 VAC 5-80-720 B	PM/PM-10
RB-331	Magnesium stearate charge	9 VAC 5-80-720 B	PM/PM-10
RB-332	Magnesium stearate charge	9 VAC 5-80-720 B	PM/PM-10
IBC (after batch transfer from RC-330 & 333)	Magnesium stearate charge	9 VAC 5-80-720 B	PM/PM-10
TA-210	Opadry II charge	9 VAC 5-80-720 B	PM/PM-10
CM-233	Tablet compressing	9 VAC 5-80-720 B	PM/PM-10
CM-234	Tablet compressing	9 VAC 5-80-720 B	PM/PM-10
CP-238	Film coating	9 VAC 5-80-720 B	PM/PM-10
CP-249	Film coating	9 VAC 5-80-720 B	PM/PM-10
TA-250/255		9 VAC 5-80-720 B	PM/PM-10
LTE-125	Low Temperature Economizer	9 VAC 5-80-720 B	PM/PM-10
LTE-127	Low Temperature Economizer	9 VAC 5-80-720 B	PM/PM-10
General	HAPs for miscellaneous coatings	9 VAC 5-80-720 B	HAPs
General	Liquid petroleum storage tanks	9 VAC 5-80-720 B	VOC / HAPs
B-7, B-8	Natural gas combustion - boilers	9 VAC 5-80-720 B	PM/PM-10

* Recognized as PM/PM-10 for purposes of visible emissions monitoring.